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Food-Drug-Cosmetic Law Journal

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The Evolution of Food Standards and the Role of the A. O. A. C. . . . . . HENRY A. LEPPER

Legislative and Administrative Progress in 1952 . . . . . C. W. CRAWFORD

Statement and Resolution on FDA . . . A. M. GILBERT

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The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need.

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REPORTS

TO THE READER

About the Authors

The article by **George Urdang** republished under the title "The Development of Pharmacopoeias" in the February, 1953 issue of this JOURNAL (Volume 8, No. 2) contains at pages 84 and 85 a list of "first editions of national pharmacopoeias" up to 1937. Recently, some later first editions have become known to the author which should be added to the list as follows:

1940—*Türk Kodeksi.*

1940—*Pharmacopoea Latviensis.*

1942—*Pharmacopoea Paraguaya.*

1947—*Pharmacopoea Bohemoslovenica.*

One statement in the list has to be corrected. According to recent research by Dr. J. Joaquin Izquierdo, it was not the 1874 edition of the *Nueva Farmacopea Mexicana* but the second edition, published in 1884, which in *1892* was given legal authority.

Furthermore, one date is to be corrected. On page 76, at line 22, the date should read 1568 instead of 1648.

It seems worth mentioning that the Third World Health Assembly, in its resolution approving the publication of the *Pharmacopea Internationalis,* recommended "the eventual inclusion of its provisions in the national pharmacopoeias after the adoption of the said provisions by the authorities responsible for the pharmacopoeias."

Henry A. Lepper, a public trustee of the Food Law Institute, has been a government career employee since December, 1913. At that time he was appointed a chemist in the Bureau of Chemistry of the United States Department of Agriculture, and assigned to the food division. He is presently Assistant Chief of the same division, Food and Drug Administration. Mr. Lepper is a native of Washington, D. C.

C. W. Crawford brings FOOD DRUG COSMETIC LAW JOURNAL readers up to date on progress of the Federal Food, Drug, and Cosmetic Act with his report for 1952. Written by the central figure in the administrative picture, his analysis is authoritative and offers another significant chapter in the story of effective enforcement activity in the United States.

Born in Texas, he spent most of his youth in Oklahoma, and received both his B. S. and M. S. degrees from Oklahoma A. & M., where he later taught chemistry. Mr. Crawford also taught at Washington State College.

During 1917, he entered the federal service as a chemist. He began his administrative career with the FDA in 1918, and has held his present position as Commissioner of Food and Drugs since June, 1951.

A statement made and resolution offered by **A. M. Gilbert** at the annual meeting of the Section on Food, Drug and Cosmetic Law of the New York Bar Association on February 20 is his contribution to this March JOURNAL. His resolution as to the inadvisability of division between two or more gov-

ernment agencies of the present jurisdiction of the FDA was unanimously adopted by the section.

Receiving his A. B. degree in 1926 from the College of the City of New York and his LL.B. degree in 1929 from Columbia University's law school, Mr. Gilbert has been continuously engaged in the practice of law, with a considerable emphasis on problems of food and drug manufacturers and distributors under federal and state laws. For over two decades, he has been particularly concerned with problems in the oleomargarine industry, and acted as counsel for that industry in proceedings which led to promulgation of the original standards of identity for margarine.

The quarterly feature "Significant Comments," by **Thomas W. Christopher** rounds out this issue of the JOURNAL. Mr. Christopher is an associate professor of law at Emory University, Atlanta, and is known to our readers not only for his "Comments," but as the writer of numerous leading articles during the past few years.

In the Federal Security Agency

Personnel changes.—Beginning with appointment of Oveta Culp Hobby as Federal Security Administrator, a number of personnel changes have been made in the Federal Security Agency: Rufus E. Miles, Jr., former Assistant Administrator for Defense Activities, is now Assistant Administrator for Program; John L. Thurston has resigned as Deputy Administrator; Jack B. Beardwood has been appointed assistant to the Administrator; Robert Ayers has been named Associate General Counsel; and Harold Packer has been appointed Assistant General Counsel.

Meetings of Food and Drug Men

New York State Bar Association Meeting.—At the February 20 meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association, the following action was taken:

(1) The section approved an amendment of the food-standards law in the Federal Food, Drug, and Cosmetic Act which confines its formal hearings to controversial issues;

(2) The chairman of the section appointed a special committee to study and report on the legal status of an international pharmacopoeia, the chairman of the committee to be Maurice W. Levy, attorney for Hoffman-La Roche, Inc.; and

(3) The officers of the section were re-elected: Charles Wesley Dunn, as chairman (for his ninth term), and James G. Flanagan, as secretary (for his second term).

American Bar Association Meeting.—The next annual meeting of the Division on Food, Drug and Cosmetic Law of the American Bar Association will be held at the Harvard University Law School in Cambridge, Massachusetts, on August 25-26, 1953.

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Journal

The Evolution of Food Standards and the Role of the A. O. A. C.

By HENRY A. LEPPER

The Author, Who Is the President of the Association of Official Agricultural Chemists, Discusses the Part Taken by That Organization in Evolving Food Standards—It Was the Knowledge Gained by the Application of the Association's Methods Which Led to Standard-Making

ONE MIGHT PRESUME from the present intricate, detailed pronouncements that standards for food are of relatively recent development. Actually, it is only the manner in which they are set up that is really new. Their promulgation as an administrative function, following procedures which are a cross between legislative and judicial operations, came with the Federal Food, Drug, and Cosmetic Act of 1938. As for the standards, the context is now more legalistically worded, but standards and definitions of identity with restrictive composition requirements were advocated and proposed before the passage of the Federal Food and Drugs Act of 1906.

How far back into antiquity concepts of standardization might go is a matter of speculation. It is not unreasonable to assume that since the time man exchanged goods, for one consideration or another, some rules or guiding principles must have been recognized and agreed upon to assure just and honest delivery. Probably the first agreements were on matters of quantity. Several references to honesty in weights and measures are found in the Old Testament; the one most familiar being, perhaps, Proverbs xi:1: "A false balance is abomina-

tion to the Lord: but a just weight is His delight." Also, by then, concepts of acceptable fitness were evident, as is reflected in the dietary laws of the Old Testament. Quality and purity are also recognized in St. Luke xiv: 34: "Salt is good: but if the salt have lost his savour wherewith shall it be seasoned?"

In America the public effort to protect the consumer was first expressed with the enactment of assizes of bread, by colonial or town assemblies, with regard to price, weight and quality. These were patterned, as were so many of the laws of that day, after those of England, where the bread assizes were enacted as early as the thirteenth century. However, progress in consumer protection with respect to weights and measures far outstripped that on standards of purity for foods.

With the culmination of the uniting of the states, one of the general powers delegated to Congress by the Constitution was fixing the standards of weights and measures. Federal laws were enacted giving expression to that authority. Many state laws and local ordinances were also enacted throughout the land to assure honesty to the consumer, respecting the quantity of food purchased. Federal authority was added to the laws of local application by the amendment of the Federal Food and Drugs Act in 1913 to provide for plain and conspicuous declaration of the quantity of contents on packages of food.

A number of definitions of adulteration and misbranding included in the 1906 law depend upon the establishment of fixed identity for enforcement. However, authority to fix standards is conspicuously missing in that law. This handicap to efficient enforcement was early recognized, but it was not until serious efforts were begun to correct the weaknesses of the 1906 law that the opportunity arose to stress the need for standards having the force and effect of statute law. One of the outstanding accomplishments of the 1938 revision as affecting control over food is the provision whereby standards can be set up. The time required by the formalities to be followed in setting up the standards has been subject to some criticism. That the situation might be improved can be expected. That the procedure for setting up standards might have been developed along different lines suggests itself.

The standards so far promulgated under the Act of 1938 are, in the main, paragons of legalistic achievement. Where considered by the courts they have, with little exception, received ready recognition. By their very comprehensiveness and completeness, all of their implica-

tions and detailed requirements are not so readily understood by the layman. Those experienced in law enforcement or engaged in the food industry during the period between the two federal laws are familiar with definitions and standards for purity of foods in simpler form. The formulation of such standards was begun well before the passage of the 1906 law. The pioneer concerted action of this undertaking was by the Association of Official Agricultural Chemists (A. O. A. C.). As organized in 1884, that association had for its objective a perfection and establishment of accurate and workable methods of analysis for fertilizers. How did it happen that an association so dedicated became engaged in the formulation of food standards?

The active membership of the association consisted of state regulatory officials who were charged with enforcement of state fertilizer laws and, although there was no corresponding federal law, members of the United States Department of Agriculture, with general interest in promoting agricultural welfare, joined in the work. Additional responsibilities on feeds for animals and on foods for humans were soon added to those of the state officials. There was a spontaneous awakening to the need for protection of the public, with its food supply. This was reflected by the passage by the states of numerous laws both general and specific during the 10 to 15 years prior to 1900.

As far back as 1879, there was an abortive attempt at the passage of a federal food law. Although the A. O. A. C. originally was engaged only on fertilizer methods, the influence of these circumstances was soon reflected in its activities. The first reference to the need for standards for food occurred early in its history. The Commissioner of Agriculture, the Honorable Norman J. Colman, then head of the United States Department of Agriculture, in his address to the second annual meeting, said:

> Of great importance, also, it seems to me, in agricultural chemical analysis is the examination of foods. It appears to me that it would be a proper function of this Association to fix standards of purity for the different kinds of food, and establish methods for the detection of adulterations which could be uniformly practiced and lead to harmonious results.

The expansion of studies of methods soon followed. By the fourth meeting, methods for feeding stuffs and dairy products were adopted. Methods for sugars and for fermented liquors soon followed. Although the progress in development of food methods was not strikingly rapid, analyses—by those then available—of commercial products and foods of known origin showed the extent of deviation from

purity of many foods being offered on the market. It was natural, therefore, that the members banded together in the A. O. A. C., although ostensibly through a common interest in methods, were led by a knowledge the methods provided, to include the sponsorship of standards, so fundamentally necessary to efficient law enforcement. Results obtained by the methods furnished the authentic data on which standards could be based.

At the 1897 meeting, the president of the A. O. A. C. called attention to the fact that:

> . . . the records of our various State food controls as amply proving that 5-15% of the entire food supply on the markets is adulterated and that fully 10% of the adulteration is injurious to health.

On the basis of such evidence, he recommended that steps be taken "to secure the establishment of standards of composition for pure food substances, just as the druggists have done for drugs." The first committee ever established on food standards in the United States was named at the same meeting from among the members of the A. O. A. C.

A. O. A. C. Committee on Food Standards Issues Printed Report

The absence of references on standards in the proceedings between the remarks by Commissioner Colman at the second convention and those of President Frear at the fourteenth convention, in 1897, would make it appear that the formal action in the appointment of the committee might have been considered precipitate. However, that the members had been giving serious thought to the problem was evidenced by the fact that within half a year after the selection of the committee the A. O. A. C. issued a printed report from its Committee on Food Standards. This report of eight pages, now very rare, sets forth the objectives to be sought, gives a list of foods under active consideration, offers suggestions to those members contributing fundamental data, and defines various forms of adulteration which standards, to be satisfactory, should aim to control. These latter definitions are for the most part included under the adulteration and misbranding provisions in the Food and Drugs Act of 1906.

It is not clear why this first report made public in 1898 did not appear in the proceedings of the fifteenth meeting of the association, held in November of the same year. It was not until the seventeenth annual convention in 1900 that a formal report was presented. This was in the nature of a progress report, listing a number of foods for

which tentative standards were under study. At the meeting the next year the list was extended. These lists showed an ambitious program. By 1903, definite standards were recommended to the Secretary of Agriculture for certain articles belonging to the meat, milk, sugar, condiment and cocoa schedules, together with their precedent definitions. Under the authority of Congress as expressed in the Appropriation Act for the Department of Agriculture for the fiscal year of 1902, the secretary proclaimed and established them for the United States of America. The report and proclamation included a statement of "principles on which the definitions and standards are based." [1] A review will disclose some of the principles as being soundly applicable to present-day standards. The principles follow:

The general consideration[s] which have guided the committee in preparing the definitions and standards for food products are the following:

1. The main classes of food articles are defined before the subordinate classes are considered.

2. The names of the various substances for which standards are proposed are defined.

3. The definitions are so framed as to exclude from the articles defined substances not included in the definitions.

4. The definitions include, where possible, those qualities which make the articles described wholesome for human food.

5. A term defined in any of the several schedules has the same meaning wherever else it is used in this report.

6. The names of food products herein defined usually agree with existing American trade or manufacturing usage, but where such usage is not clearly established or where trade names confuse two or more articles for which specific designations are desirable, preference is given to one of the several trade names applied.

7. Standards are based upon data representing materials produced under American conditions and manufactured by American processes or representing such varieties of foreign articles as are chiefly imported for American use.

8. The standards fixed are such that a departure of the articles to which they apply, above the maximum or below the minimum limit prescribed is evidence that such articles are of inferior or abnormal quality.

9. The limits fixed as standard are not necessarily the extremes authentically recorded for the article in question, because such extremes are commonly due to abnormal conditions of production and are usually accompanied by marks of inferiority or abnormality readily perceived by the producer or manufacturer.

The authority carried in the Appropriation Act of 1902 was:

. . . to enable the Secretary of Agriculture in collaboration with the Association of Official Agricultural Chemists and such other experts as he may deem necessary, to establish standards of purity for food products and to determine what are regarded as adulterations therein for the guidance of the various states and courts of Justice.

[1] Bureau of Chemistry Bulletin No. 81 (1904), p. 180; United States Department of Agriculture, Office of the Secretary, Circular No. 10 (November 20, 1903).

This authority was continued in the subsequent appropriation acts from 1903 to 1907. In the acts for 1906 and 1907, the words "for the guidance of various states and courts of Justice" were deleted. Although the committee of the A. O. A. C. continued its activities, only general reports appeared in the association's proceedings. The details of the additional standards recommended were approved by the Secretary of Agriculture, and henceforth published by the department. In 1904,[2] the standards were supplemented by those on grains and meals, refiners syrup, honey, wine and vinegar and, in 1906,[3] by those for fruit and fruit products, flavoring extracts, edible vegetable oils, and salt.

Again, in 1906,[4] just prior to the signing of the Federal Food and Drugs Act of that year, additional standards were announced for ice cream, dried and canned vegetables, pickles, sauerkraut, ketchup, tea and coffee. The reason full reports of the standards committee did not appear in the proceedings of the A. O. A. C. may have been to avoid duplication, because the proceedings of the association at that time were also published by the department. This could illustrate the close association of the work of the A. O. A. C. with that of the department.

Such legal status as the standards had, by authority of the appropriation acts, was not perpetuated by a provision on standard-making in the food law of 1906. A review of the legislative history of that law permits an insight as to why such authority was not continued. A movement for a federal law began 27 years prior to 1906. Legislation on the subject was continuously before Congress. Of the bills on the general subject offered during those years, 16 were reported out by committees. One bill passed the Senate as early as 1892 and two passed the House in 1902 and 1904, but concurrent action by both Houses did not succeed until 1906. The early bills had little resemblance to the final enactment, but those proposed later were of closer similarity. It was in some of the latter bills, where definitions of adulteration were set forth, that the concept of authorizing the Secretary of Agriculture to fix standards for food was introduced. Such provision first appeared in the Faulkner Bill.[5] The bill was favorably reported by

[2] United States Department of Agriculture, Office of the Secretary, Circular No. 13 (December 20, 1904).

[3] United States Department of Agriculture, Office of the Secretary, Circular No. 17 (March 8, 1906).

[4] United States Department of Agriculture, Office of the Secretary, Circular No. 19 (June 26, 1906).

[5] S. 4144, 55th Cong.

the Committee on Agriculture and Forestry on January 17, 1899, but no further action was taken on it.

Specific Recognition of A. O. A. C. as Authority

In Section 8 of that bill, the A. O. A. C. was recognized by name as the authoritative source on standards. It also provided consultation with five physicians, and that the standards "shall be the standards before all courts." The provisions of the Faulkner Bill, expanded to include authority to determine wholesomeness or unwholesomeness of preservatives and to add five experts to the committee to be consulted by the secretary in setting up the standards, were repeated in the Brosius Bill [6] which was reported the next year to the House by the Committee on Interstate and Foreign Commerce.

Section 7 of that bill read:

> . . . that it shall be the duty of the Secretary of Agriculture to fix standards of food products when advisable, and to determine the wholesomeness or unwholesomeness of preservatives and other substances which are or may be added to foods, and to aid him in reaching just decisions in such matters he is authorized to call upon the Director of Bureau of Chemistry and the chairman of the committee on food standards of the Association of Official Agricultural Chemists, and such physicians, not less than five, as the President of the United States shall select, three of whom shall be from the Medical Departments of the Army, the Navy, and the Marine-Hospital Service, and not less than five experts, to be selected by the Secretary of Agriculture by reason of their attainments in physiological chemistry, hygiene, commerce, and manufactures, to consider jointly the standards of all food products (within the meaning of this Act) and to study the effect of preservatives and other substances added to food products on the health of the consumer; and when so determined and approved by the Secretary of Agriculture such standards shall guide the chemists of the Department of Agriculture in the performance of the duties imposed upon them by this Act and shall remain the standards before all the United States Courts. It shall be the duty of the Secretary of Agriculture, either directly or through the director of the bureau of chemistry and the chairman of the committee on food standards of the Association of Official Agricultural Chemists and the medical officers and experts before mentioned, to confer with and consult, when so requested, the duly accredited representatives of all industries producing articles for which standards shall be established under the provisions of this Act.

Further action was not taken on this bill.

To those experienced with the applications of the federal food law, the cumbersome procedure of that provision is obvious. It is of interest, however, to note the attempt to provide a recognition of the standards by the courts. What force and effect the standards may have actually had before the courts was, of course, never determined. In 1900, the Hepburn Bill [7] was introduced into the House. It carried

[6] H. R. 9677, 56th Cong.

[7] H. R. 3109, 57th Cong.

as Section 7 the same provision for standards as the Brosius Bill. In place of the words "shall remain the standards before all the United States Courts," were the words:

> . . . may be read in evidence in the United States Courts, but shall not be considered as determining the adulteration of any articles under section six [defining adulteration of food practically as was done in the law of 1906] of this Act until such standards and determinations are approved in the courts.

In the draft reported out by the committee, the words "until such standards and determinations are approved by the courts" were deleted. The bill in the amended form passed the House on December 19, 1902. On January 19, 1904, the House passed a second Hepburn Bill,[8] wherein the provision on standard-making had been greatly simplified as follows:

> Section 7. That it shall be the duty of the Secretary of Agriculture to fix standards of food products when advisable, for the guidance of officials charged with the administration of food laws and for the information of the courts, and to determine the wholesomeness or unwholesomeness of preservatives and other substances which are or may be added to foods, and to aid him in reaching just decisions in such matters he is authorized to call upon the committee on food standards of the Association of Official Agricultural Chemists, and such other experts as he may deem necessary.

Heyburn Bill Substituted for Hepburn Bill

The revision of the original language and the toned-down wording of the second Hepburn bill namely "for the information of the courts" reflected the uncertainty being expressed at that time on whether Congress had the power to delegate authority to set up standards which would be binding on the courts. Recognition of standards by the courts was suggested, but not mandatory. After the passage of the Hepburn Bill by the House, the committee of the Senate substituted the Heyburn Bill,[9] which finally became the law of 1906. It carried no section on food standards. The authority to fix standards seemed to be the major issue, between the legislative bodies, on which the House surrendered in concurring in the passage of the Heyburn Bill.

During the final debate in the Senate, the influences behind the objection to granting authority to fix standards might be surmised. In an extension of remarks for the record,[10] the following criticism was offered:

> The Hepburn Bill in the House is almost a counterpart of the Heyburn Bill, but contains another objectionable and unfair feature. It provides, in section 7, that the Secretary of Agriculture, shall fix standards of food products for the

[8] H. R. 6295, 58th Cong.
[9] S. 88, 59th Cong.
[10] 40 *Congressional Record* 2659, part 3.

guidance of officials enforcing the law and for the information of the courts, and determine the wholesomeness and unwholesomeness of preservatives and other substances used in food. This means that we would have to wait for the establishment of those standards before we could tell the effect of the law. The food manufacturers of the country are decidedly opposed to giving the Secretary of Agriculture, or any other official, the arbitrary power to regulate the food supply of the country, and they insist that in framing up such standards and in the determination of such issues they have a voice and a vote, either directly or through their duly elected representatives in Congress.

The food manufacturers referred to were organized as the "National Food Manufacturers' Association."

A substitute bill sponsored by that association was offered [11] on the Senate floor, wherein the ultimate of opposition—a prohibition of the fixing of standards—was set forth in Section 13, as follows:

That this Act shall not be construed by any specific standards for food not incorporated herein; but in any proceedings herein under the commonly accepted standard for any article of food upon which such proceeding shall have been commenced shall, when not in conflict with the provision of this Act, be the guide in determining whether or not the provisions of this Act have been violated: *Provided,* that this section shall not contravene any of the provisions of this Act expressly permitting added substances in articles of food.

By a vote of the Senate the substitute bill was rejected.

In the extension of remarks, above referred to, Section 13 of the substitute bill was explained as follows:

This section prevents the possibility of any specific standards for food being used and given the effect of law in prosecutions under this bill. It is not proper that the standards of any person or persons should be consulted to the exclusion of others just as good or better under any law. With drugs it is somewhat different, as the standard for them relates to their strength only, whereas the standards for food relate to the ingredients, methods of preparation, etc., and those are so varied that it is a far more difficult matter to adjust than it is to fix a standard for drugs. This section recognizes the principle that if any standards for food are to be given effect they should be duly considered by the representatives of the people to be incorporated into a law. It is necessary to take the precaution which is taken in this section in order not to have the law misconstrued, as some of our State Supreme Courts have already given full effect to private standards not mentioned in any law (*State v. Jennings* Mich.). This bill practically establishes standards for all articles specifying what are below standard; and it leaves the question of whether an article is a standard article or not to be proved as any other matter of fact is proved by law, by the best evidence obtainable, if it is desired to offer it; and it recognizes the fact that a jury of intelligent American citizens are capable of determining under the proper evidence, whether an article of food is a standard article or not or whether it has been prepared in a standard and proper way or not.

This proviso also protects food that contains natural preservatives and which is now sometimes prosecuted under State food laws.

[11] Reference cited at footnote 10, at p. 2771.

Although the prohibition on standard-making was rejected, the ends intended were accomplished by the simple expedient of failure to provide authority to fix standards in the law that was passed. Incidentally, there were other provisions of the substitute bill that officials experienced in food-law enforcement will now recognize as ineffective in the protection of the public. To complete the extension of remarks there is a listing of some 171 firms as the members of the National Food Manufacturers' Association. Among them can be recognized leading food manufacturers, wholesalers and distributors of that day. Of greater interest at this time, when issues concerning the addition of chemicals to food are being given foremost consideration in food legislation, is the inclusion of the names of many manufacturers of chemicals. It requires only a little imagination to understand their membership in an association of *food manufacturers*.

After meeting with the conferees on the Hepburn Bill as passed by the House and the Heyburn Bill as passed by the Senate, the report to the Senate on the conference agreement stated: [12]

> Now what have we eliminated from this bill? Senators will remember that the House measure provided for the fixing of standards and it called to the assistance of the Secretary of Agriculture certain experts who were to aid him in determining what the standards should be, and also provided that the standards so established by them should be for the guidance of the court. The senate has always contended [The Padock Bill, S. 1, Fifty-second Congress, the only other bill passed by the Senate, March 9, 1892, made no reference to standards for food. It did not do so as originally introduced as S. 3991, Fifty-first Congress] that the power to fix standards should never be given to any man, and the House conferees receded from that position of the House amendment and it goes out.

In the "Statement of Managers on Part of the House," [13] while the section on standards "goes out" as so emphatically stated to the Senate, the explanation in the discussion of why the House conferees receded is enlightening, as the following shows:

> Mr. Mann. I may say to the House that the bill as reported by the conferees is substantially the bill passed by the House, with a few exceptions. We struck out in conference the section requiring the Secretary of Agriculture to determine the standards of Food. . . .
>
> Mr. Pollard. I believe the gentleman made the statement that the conference struck out the House provisions that the Secretary of Agriculture should determine what the standards should be? Mr. Mann. That section goes out entirely in the conference report.
>
> Mr. Pollard. Was any change made in the provision of the House wherein we provided that a board of five inspectors should be selected to pass upon the wholesomeness or deleteriousness of foods?

[12] Reference cited at footnote 10, at p. 9496, part 10.

[13] Reference cited at footnote 10, at p. 9737, part 10.

Mr. Mann. That provision was in section 9 directing the Secretary of Agriculture to determine standards and the entire section goes out.

Mr. Pollard. If that is the case who determines whether a preservative that is used is poisonous or deleterious to health?

Mr. Mann. Mr. Speaker as I stated in the House when the bill was before the House it is the courts which must determine in the end as to the question of the wholesomeness or the deleteriousness of preservatives or of any article of food. The only object in having that provision in the bill requiring the Secretary of Agriculture to determine standards was for the purpose of governing prosecutions and provide uinformity and give to producers in advance of prosecution knowledge of the requirements insisted upon by officials in charge; but the Senate conferees were unalterably opposed to that provision, and as it was not an essential provision of the law we gave way on that provision in order to save the rest of the bill practically intact as the House had enacted it.

Mr. Cooper of Wisconsin. From such study as I have been able to give the bill it seems to me a good measure; but I should like to put to the gentleman one question in line with the question that was asked by the gentleman from Nebraska (Mr. Pollard) and that is on the matter of the standards. In the report submitted by the committee on interstate commerce [on] this bill I find this cause [sic] on page 4. "It is however essential to the success and operation of any pure food measure that standards of food products shall be arrived at for the guidance of the officials charged with the administration of the law and often for the information of the court." And a little later it says "It was therefore provided in the bill that the Secretary of Agriculture . . ." And so forth. That report states it is essential for the success and operation of any pure-food law to have standards established by the Secretary. Now, I presume that the conferees have reached the conclusion, in view of some provisions of the bill, that would justify a reversal of that opinion, and I should like to hear from the gentleman from Illinois on that subject.

Mr. Mann. Mr. Speaker when the report on this bill in the House was written I did say in the report that it was essential to the success of a pure-food bill. It is essential to the best success of a pure-food bill that the Secretary of Agriculture or some other official shall determine the standards, but the gentleman from Wisconsin certainly has enough understanding of language to know that nothing in the world is *absolutely* "essential" in legislation. We do not have the bill exactly as we wanted it but so far as the final features of the bill are concerned we have them contained in the bill as it comes back to the House. I may state to the House further that, under the law as it now stands in the agriculture appropriation bill [the authority in the Appropriation Act was discontinued after July, 1907], the Secretary of Agriculture is authorized to pick standards of foods; and while I do not believe that is sufficient legislation, and while for one I would be willing to consent that the Secretary of Agriculture should have the arbitrary power to determine what is adulterated or misbranded food, I do think that the provision that the House committee brought into the House as section 9, as amended in the House at my suggestion, was, on the whole, the most perfect provision upon the subject of fixing standards which has ever been before the House, . . . and I regret extremely that we met a stone wall on that section of the bill in the determined opposition of the Senate conferees. The existing law however is entirely sufficient for the operation of the pure-food law.

Neither of the statements to the Houses of Congress permits a clear conclusion as to the reason of the adamant attitude of the Senate. It can be noted that the decision on questions of the wholesomeness and

the use of preservatives were included in the authority to be granted the secretary, along with standard-making power. It is well known among those actively interested in the legislation that the food industry, in general, at that time was against limitation of preservatives; but it was not good business to too openly oppose efforts to prohibit added substances which might render foods harmful. Accordingly, the question of making standards permitted a more favorable atmosphere as grounds for opposition. At the same time, the elimination of the section for providing standards would carry along into discard the more objectionable curb on preservatives, and thereby avoid unfavorable publicity.

At that time reasoning was advanced as is stated above that Congress should not or could not delegate its authority to legislate standards. This was claimed also in many other quarters. The very stress used in attempting to differentiate between providing just such authority in the case of drugs while refusing it for foods illustrates the untenability of the position. The first reference to the United States Pharmacopoeia as the authority on purity for drugs appeared in an early bill,[14] favorably reported to the House in 1882, wherein drugs were defined as adulterated: "1st, If or when sold by a name recognized in the United States Pharmacopoeia it differs from the standard of strength, quality or purity as laid down therein." There was no material deviation in all the following bills from the principle thus established. This principle eventually came to be included in both the 1906 and 1938 laws. No serious opposition was voiced to this provision on drugs, although as a delegation of power as compared to that proposed on food standards, it appears to be a distinction without a difference. Was there a lack of sincerity in advancing an objection to a like procedure on foods?

There has been no successful challenge to the provision on the United States Pharmacopoeia. In one case, the federal judge ruled to the effect that Congress, in providing that a drug shall be deemed to be adulterated if it fails to comply with the standard of such drug, as determined by the tests laid down by the United States Pharmacopoeia or National Formulary, official at the time of investigation, did not delegate legislative power, but merely described a method of ascertaining facts upon which the operation of the statute was to depend. In another case, a federal judge ruled that Congress has the right in the interest of the general public and in the exercise of its control over

[14] H. R. 1087, 47th Cong.

interstate commerce to prescribe the standard up to which certain drugs must come when they are shipped in interstate commerce. The attack on constitutional grounds was thus denied. Neither case was appealed. Under the 1938 law, there has also been only one challenge, and in it the validity was not decided. Had attempt been made in the 1906 law to give status to standards set up by the secretary, formulated by cooperation with the A. O. A. C., the question of legality would likely have been raised early in the law's enforcement. It is only speculation to say that the courts would have denied Congress the right to make such provision.

Effect of Limitations: Ineffective Enforcement

The fact that standard-making was included in the law would have been, in itself, a recognition of its need and importance. With this principle established, an adverse decision on the manner by which the standards had been set up would no doubt have led to remedial legislation in keeping with the restrictions which the judicial branch probably would have enunciated. Thus, in any event, those indispensable tools in controlling many of the violations of adulterations and misbranding would have been available from the beginning. As it was, the limitations associated with the standards, being only advisory, placed a premium on ineffective enforcement.

Mr. Walter G. Campbell, reporting [15] on the features of the proposed new law (1938) and on what was needed to be accomplished, summarized the situation that existed over the years, on standards, as follows:

> 6. The present law gives the Department of Agriculture no authority to establish legal standards for food products, except in the limited field of canned foods. The food standards announced by the Department are wholly advisory in character and compliance is a voluntary matter on the part of the manufacturer. Such advisory standards are based upon the consensus of consumer understanding and upon good manufacturing practice. To prove that a product sold within the jurisdiction of the Food and Drugs Act and that fails to comply with the advisory standard is adulterated or misbranded, it is necessary for the Department to present to the court and jury convincing evidence that the advisory standard does represent the actual composition of the product expected by the consumer and recognized by the majority of the trade. Proof that the food on trial does not meet the advisory standard is of no avail unless the validity of the standard is first established. This imposes a double burden of proof upon the Government as well as the expense of bringing into court trade and consumer witnesses who are prepared to testify that the advisory standard accurately represents the material in question. It has long been recognized that this necessity imposes a handicap

[15] Annual Report of the Chief of the Food and Drug Administration, 1933.

of undue proportions upon the Government and that the lack of legal standards is a distinct disadvantage to ethical manufacturers who are forced to compete with products which differ from the advisory standards. The establishment of food standards having the force and effect of law will vastly simplify the problem of enforcement and will unquestionably be of great advantage to the consuming public and to the manufacturer of legal products.

The establishment of standards was not abandoned with the Act of 1906; instead, the Secretary of Agriculture appointed a committee known as the United States Commission on Purity of Foods. The commission included the Association of Official Agricultural Chemists food standards committee, and one appointed by and for the Association of State and National Food and Dairy Departments (now the Association of Food and Drug Officials of the United States). The commission functioned as such until 1913, when the Secretary of Agriculture appointed a Joint Committee on Definitions and Standards, consisting of nine members—three from the Department of Agriculture; three from the Association of Dairy, Food, and Drug Officials; and three from the Association of Official Agricultural Chemists. This committee met at least once a year, and usually more often, until 1933. Its last meeting was held in 1937.

With the formation of the joint committee, the standards committee of the A. O. A. C. discontinued its formal activity as an association function. Such activities in the association continued through its members on the joint committee. The A. O. A. C. standards committee, in the nine years from its inception in 1897 to 1906, formulated more than 200 definitions and standards published in the Department of Agriculture, Office of the Secretary, Circular 19. Through its further cooperation and, later, through that of members of the association, the total approached nearly 300 by 1937. They are now prologue. Their value is largely historical. It is obvious that had circumstances and events been different, they might be today the standards for food, although experience with them as legal instruments might have brought about expansion and augmentation of details to meet such requirements as are now considered essential.

With the passage of the Act of 1938, the joint committee was superseded by a standards committee set up in the Food and Drug Administration, composed of four experienced state food-law enforcement officers and two representatives of the Food and Drug Administration. Dr. P. B. Dunbar, in a message before the A. O. A. C. in 1939,[16] described the function of that body as follows:

[16] 23 *Journal of the Association of Official Agricultural Chemists* 35 (1940).

The Standards Committee, in cooperation with the Administrative offices of the Administration, determines what foods shall be standardized, evaluates available data in support of a definition and standard, outlines to the field forces of the Administration additional data to be acquired, obtains the views of consumers and the trade, and eventually formulates tentative specifications for definitions and standards. These specifications are considered by the Administration and with the aid of the Solicitor's office are placed in proper form for announcement of public hearings before a representative of the Secretary.

Members of the A. O. A. C. are no longer officially recognized on the committee, although state food-law enforcement officers are more often than not among its members. The A. O. A. C. has completed the circle. In the beginning it was the knowledge gained by the application of its methods which led to standard-making. Now, again, it is by the output of results by its methods that information is established fundamental to a basis of the requirements of composition and purity in standards. At the same time, the methods serve to judge compliance.

[The End]

Annex A*

UNITED STATES DEPARTMENT OF AGRICULTURE,

OFFICE OF THE SECRETARY.—Circular No. 19.

Standards of Purity for Food Products

Superseding Circulars Nos. 13 and 17.

Supplemental Proclamation.

Referring to Circular No. 13 of this Office, dated December 20, 1904, and to Circular No. 17 of this Office, dated March 8, 1906, the following food standards are hereby established as superseding and supplemental to those proclaimed on the dates above named.

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *June 26, 1906.*

Letter of Submittal.

The Honorable the SECRETARY OF AGRICULTURE.

SIR: The undersigned, representing the Association of Official Agricultural Chemists of the United States and the Interstate Food Commission, and commissioned by you, under authority given by the act of Congress approved March 3, 1903, to collaborate with you "to establish standards of purity for food products and to determine what are regarded as adulterations therein," respectfully report that they have carefully reviewed, in the light of recent investigations and correspondence, the standards earlier recommended by them and have prepared a set of amended schedules, in which certain changes have been introduced for the purpose of securing increased accuracy of expression and a more perfect corre-

* [Editor's Note: Annex A contains the advisory food standards published by the United States Department of Agriculture in Circular No. 19, on June 26, 1906, which were effective when the original Federal Food and Drugs Act was enacted and which were first officially used in its administration.]

spondence of the chemical limits to the normal materials designated, and from which standards previously proclaimed for several manufactured articles have been omitted because of the unsatisfactory condition of trade nomenclature as applied thereto; and also additional schedules of standards for ice creams, vegetables and vegetable products, tea and coffee. They respectfully recommend that the standards herewith submitted be approved and proclaimed as the established standards, superseding and supplementing those established on December 20, 1904, and March 8, 1906.

The principles that have guided us in the formulation of these standards are appended hereto.

The several schedules of additional standards recommended have been submitted, in a tentative form, to the manufacturing firms and the trade immediately interested, and also to the State food-control officials for criticism.

Respectfully,

WILLIAM FREAR,
EDWARD H. JENKINS,
M. A. SCOVELL,
H. A. WEBER,
H. W. WILEY,
Committee on Food Standards,
Association of Official Agricultural Chemists.
RICHARD FISCHER,
Representing the Interstate Food Commission

WASHINGTON, D. C., *June 26, 1906.*

Principles on Which the Standards Are Based.

The general considerations which have guided the committee in preparing the standards for food products are the following:

1. The standards are expressed in the form of definitions, with or without accompanying specifications of limit in composition.

2. The main classes of food articles are defined before the subordinate classes are considered.

3. The definitions are so framed as to exclude from the articles defined substances not included in the definitions.

4. The definitions include, where possible, those qualities which make the articles described wholesome for human food.

5. A term defined in any of the several schedules has the same meaning wherever else it is used in this report.

6. The names of food products herein defined usually agree with existing American trade or manufacturing usage; but where such usage is not clearly established or where trade names confuse two or more articles for which specific designations are desirable, preference is given to one of the several trade names applied.

7. Standards are based upon data representing materials produced under American conditions and manufactured by American processes or representing such varieties of foreign articles as are chiefly imported for American use.

8. The standards fixed are such that a departure of the articles to which they apply, above the maximum or below the minimum limit prescribed, is evidence that such articles are of inferior or abnormal quality.

9. The limits fixed as standard are not necessarily the extremes authentically recorded for the article in question, because such extremes are commonly due

to abnormal conditions of production and are usually accompanied by marks of inferiority or abnormality readily perceived by the producer or manufacturer.

FOOD STANDARDS.

I. ANIMAL PRODUCTS.

A. Meats and the Principal Meat Products.

a. MEATS.

1. *Meat, flesh,* is any clean, sound, dressed, and properly prepared edible part of animals in good health at the time of slaughter, and if it bears a name descriptive of its kind, composition, or origin, it corresponds thereto. The term "animals", as herein used, includes not only mammals, but fish, fowl, crustaceans, mollusks, and all other animals used as food.

2. *Fresh meat* is meat from animals recently slaughtered and properly cooled until delivered to the consumer.

3. *Cold storage meat* is meat from animals recently slaughtered and preserved by refrigeration until delivered to the consumer.[a]

4. *Salted, pickled,* and *smoked meats* are unmixed meats preserved by salt, sugar, vinegar, spices, or smoke, singly or in combination, whether in bulk or in suitable containers.[b]

b. MANUFACTURED MEATS.

1. *Manufactured meats* are meats not included in paragraphs 2, 3, and 4, whether simple or mixed, whole or comminuted, in bulk or in suitable containers,[b] with or without the addition of salt, sugar, vinegar, spices, smoke, oils, or rendered fat. If they bear names descriptive of kind, composition, or origin, they correspond thereto and when bearing such descriptive names, if force or flavoring meats are used, the kind and quantity thereof are made known.

c. MEAT EXTRACTS, MEAT PEPTONES, ETC.

(Schedule in preparation.)

d. LARD.

1. *Lard* is the rendered fresh fat from hogs in good health at the time of slaughter, is clean, free from rancidity, and contains, necessarily incorporated in the process of rendering, not more than one (1) per cent of substances, other than fatty acids and fat.

2. *Leaf lard* is lard rendered at moderately high temperatures from the internal fat of the abdomen of the hog, excluding that adherent to the intestines, and has an iodin number not greater than sixty (60).

3. *Neutral lard* is lard rendered at low temperatures.

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[a] The establishment of proper periods of time for cold storage is reserved for future consideration when the investigations on this subject, authorized by Congress, are completed.

[b] Suitable containers for keeping moist food products such as sirups, honey, condensed milk, soups, meat extracts, meats, manufactured meats, and undried fruits and vegetables, and wrappers in contact with food products, contain on their surfaces, in contact with the food product, no lead, antimony, arsenic, zinc or copper or any compounds thereof or any other poisonous or injurious substance. If the containers are made of tin plate they are outside-soldered and the plate in no place contains less than one hundred and thirteen (113) milligrams of tin on a piece five (5) centimeters square or one and eight-tenths (1.8) grains on a piece two (2) inches square.

The inner coating of the containers is free from pin holes, blisters, and cracks.

If the tin plate is lacquered, the lacquer completely covers the tinned surface within the container and yields to the contents of the container no lead, antimony, arsenic, zinc or copper or any compounds thereof, or any other poisonous or injurious substance.

B. Milk and Its Products.

a. MILKS.

1. *Milk* is the fresh, clean, lacteal secretion obtained by the complete milking of one or more healthy cows, properly fed and kept, excluding that obtained within fifteen days before and ten days after calving, and contains not less than eight and one-half (8.5) per cent of solids not fat, and not less than three and one-quarter (3.25) per cent of milk fat.

2. *Blended milk* is milk modified in its composition so as to have a definite and stated percentage of one or more of its constituents.

3. *Skim milk* is milk from which a part or all of the cream has been removed and contains not less than nine and one-quarter (9.25) per cent of milk solids.

4. *Pasteurized milk* is milk that has been heated below boiling but sufficiently to kill most of the active organisms present and immediately cooled to 50° Fahr. or lower.

5. *Sterilized milk* is milk that has been heated at the temperature of boiling water or higher for a length of time sufficient to kill all organisms present.

6. *Condensed milk, evaporated milk,* is milk from which a considerable portion of water has been evaporated and contains not less than twenty-eight (28) per cent of milk solids of which not less than twenty-seven and five-tenths (27.5) per cent is milk fat.

7. *Sweetened condensed milk* is milk from which a considerable portion of water has been evaporated and to which sugar (sucrose) has been added, and contains not less than twenty-eight (28) per cent of milk solids, of which not less than twenty-seven and five-tenths (27.5) per cent is milk fat.

8. *Condensed skim milk* is skim milk from which a considerable portion of water has been evaporated.

9. *Buttermilk* is the product that remains when butter is removed from milk or cream in the process of churning.

10. *Goat's milk, ewe's milk, et cetera,* are the fresh, clean, lacteal secretions, free from colostrum, obtained by the complete milking of healthy animals other than cows, properly fed and kept, and conform in name to the species of animal from which they are obtained.

b. CREAM.

1. *Cream* is that portion of milk, rich in milk fat, which rises to the surface of milk on standing, or is separated from it by centrifugal force, is fresh and clean and contains not less than eighteen (18) per cent of milk fat.

2. *Evaporated cream, clotted cream,* is cream from which a considerable portion of water has been evaporated.

c. MILK FAT OR BUTTER FAT.

1. *Milk fat, butter fat,* is the fat of milk and has a Reichert-Meissl number not less than twenty-four (24) and a specific gravity not less than 0.905 $\left(\frac{40^\circ \text{ C.}}{40^\circ \text{ C.}} \right)$

d. BUTTER.

1. *Butter* is the clean, non-rancid product made by gathering in any manner the fat of fresh or ripened milk or cream into a mass, which also contains a small portion of the other milk constituents, with or without salt, and contains not less than eighty-two and five-tenths (82.5) per cent of milk fat. By acts of Congress

approved August 2, 1886, and May 9, 1902, butter may also contain added coloring matter.

2. *Renovated butter, process butter,* is the product made by melting butter and reworking, without the addition or use of chemicals or any substances except milk, cream, or salt, and contains not more than sixteen (16) per cent of water and at least eighty-two and five-tenths (82.5) per cent of milk fat.

e. CHEESE.

1. *Cheese* is the sound, solid, and ripened product made from milk or cream by coagulating the casein thereof with rennet or lactic acid, with or without the addition of ripening ferments and seasoning, and contains, in the water-free substance, not less than fifty (50) per cent of milk fat. By act of Congress, approved June 6, 1896, cheese may also contain added coloring matter.

2. *Skim milk cheese* is the sound, solid, and ripened product, made from skim milk by coagulating the casein thereof with rennet or lactic acid, with or without the addition of ripening ferments and seasoning.

3. *Goat's milk cheese, ewe's milk cheese, et cetera,* are the sound, ripened products made from the milks of the animals specified, by coagulating the casein thereof with rennet or lactic acid, with or without the addition of ripening ferments and seasoning.

f. ICE CREAMS.

1. *Ice cream* is a frozen product made from cream and sugar, with or without a natural flavoring, and contains not less than fourteen (14) per cent of milk fat.

2. *Fruit ice cream* is a frozen product made from cream, sugar, and sound, clean, mature fruits, and contains not less than twelve (12) per cent of milk fat.

3. *Nut ice cream* is a frozen product made from cream, sugar, and sound, nonrancid nuts, and contains not less than twelve (12) per cent of milk fat.

g. MISCELLANEOUS MILK PRODUCTS.

1. *Whey* is the product remaining after the removal of fat and casein from milk in the process of cheese-making.

2. *Kumiss* is the product made by the alcoholic fermentation of mare's or cow's milk.

II. VEGETABLE PRODUCTS.

A. GRAIN PRODUCTS.

a. GRAINS AND MEALS.

1. *Grain* is the fully matured, clean, sound, air-dry seed of wheat, maize, rice, oats, rye, buckwheat, barley, sorghum, millet, or spelt.

2. *Meal* is the clean, sound product made by grinding grain.

3. *Flour* is the fine, clean, sound product made by bolting wheat meal and contains not more than thirteen and one-half (13.5) per cent of moisture, not less than one and twenty-five hundredths (1.25) per cent of nitrogen, not more than one (1) per cent of ash, and not more than fifty hundredths (0.50) per cent of fiber.

4. *Graham flour* is unbolted wheat meal.

5. *Gluten flour* is the clean, sound product made from flour by the removal of starch and contains not less than five and six-tenths (5.6) per cent of nitrogen and not more than ten (10) per cent of moisture.

6. *Maize meal, corn meal, Indian corn meal,* is meal made from sound maize grain and contains not more than fourteen (14) per cent of moisture, not less than one and twelve hundredths (1.12) per cent of nitrogen, and not more than one and six-tenths (1.6) per cent of ash.

7. *Rice* is the hulled, or hulled and polished grain of *Oryza sativa*.

8. *Oatmeal* is meal made from hulled oats and contains not more than twelve (12) per cent of moisture, not more than one and five-tenths (1.5) per cent of crude fiber, not less than two and twenty-four hundredths (2.24) per cent of nitrogen, and not more than two and two-tenths (2.2) per cent of ash.

9. *Rye flour* is the fine, clean, sound product made by bolting rye meal and contains not more than thirteen and one-half (13.5) per cent of moisture, not less than one and thirty-six hundredths (1.36) per cent of nitrogen, and not more than one and twenty-five hundredths (1.25) per cent of ash.

10. *Buckwheat flour* is bolted buckwheat meal and contains not more than twelve (12) per cent of moisture, not less than one and twenty-eight hundredths (1.28) per cent of nitrogen, and not more than one and seventy-five hundredths (1.75) per cent of ash.

B. Fruit and Vegetables.

a. Fruit and Fruit Products.

(Except fruit juices, fresh, sweet, and fermented, and vinegars.)

1. *Fruits* are the clean, sound, edible, fleshy fructifications of plants, distinguished by their sweet, acid, and ethereal flavors.

2. *Dried fruit*[a] is the clean, sound product made by drying mature, properly prepared, fresh fruit in such a way as to take up no harmful substance, and conforms in name to the fruit used in its preparation; *sun-dried fruit* is dried fruit made by drying without the use of artificial means; *evaporated fruit* is dried fruit made by drying with the use of artificial means.

3. *Evaporated apples* are evaporated fruit made from peeled and cored apples, and contain not more than twenty-seven (27) per cent of moisture determined by the usual commercial method of drying for four (4) hours at the temperature of boiling water.

(Standards for other dried fruits are in preparation.)

4. *Canned fruit* is the sound product made by sterilizing clean, sound, properly matured and prepared fresh fruit, by heating, with or without sugar (sucrose) and spices, and keeping in suitable, clean, hermetically sealed containers and conforms in name to the fruit used in its preparation.

5. *Preserve*[b] is the sound product made from clean, sound, properly matured and prepared fresh fruit and sugar (sucrose) sirup, with or without spices or vinegar, and conforms in name to that of the fruit used, and in its preparation not less than forty-five (45) pounds of fruit are used to each fifty-five (55) pounds of sugar.

6. *Honey preserve*[b] is preserve in which honey is used in place of sugar (sucrose) sirup.

7. *Glucose preserve*[b] is preserve in which a glucose product is used in place of sugar (sucrose) sirup.

8. *Jam, marmalade,*[b] is the sound product made from clean, sound, properly matured and prepared fresh fruit and sugar (sucrose), with or without spices or vinegar, by boiling to a pulpy or semisolid consistence, and conforms in name to the fruit used, and in its preparation not less than forty-five (45) pounds of fruit are used to each fifty-five (55) pounds of sugar.

9. *Glucose jam, glucose marmalade,*[b] is jam in which a glucose product is used in place of sugar (sucrose).

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[a] The subject of sulphurous acid in dried fruits is reserved for consideration in connection with the schedule "Preservatives and Coloring Matters."

[b] Products made with mixtures of sugar, glucose, and honey, or any two thereof, are reserved for future consideration.

10. *Fruit butter*[*] is the sound product made from fruit juice and clean, sound, properly matured and prepared fruit, evaporated to a semisolid mass of homogeneous consistence, with or without the addition of sugar and spices or vinegar, and conforms in name to the fruit used in its preparation.

11. *Glucose fruit butter*[*] is fruit butter in which a glucose product is used in place of sugar (sucrose).

12. *Jelly*[*] is the sound, semisolid, gelatinous product made by boiling clean, sound, properly matured and prepared fresh fruit with water, concentrating the expressed and strained juice, to which sugar (sucrose) is added, and conforms in name to the fruit used in its preparation.

13. *Glucose jelly*[*] is jelly in which a glucose product is used in place of sugar (sucrose).

b. VEGETABLES AND VEGETABLE PRODUCTS

1. *Vegetables* are the succulent, clean, sound, edible parts of herbaceous plants used for culinary purposes.

2. *Dried vegetables* are the clean, sound products made by drying properly matured and prepared vegetables in such a way as to take up no harmful substance, and conform in name to the vegetables used in their preparation; *sun-dried vegetables* are dried vegetables made by drying without the use of artificial means; *evaporated vegetables* are dried vegetables made by drying with the use of artificial means.

3. *Canned vegetables* are sound, properly matured and prepared fresh vegetables, with or without salt, sterilized by heat, with or without previous cooking in vessels from which they take up no metallic substance, kept in suitable, clean, hermetically sealed containers, are sound and conform in name to the vegetables used in their preparation.

4. *Pickles* are clean, sound, immature cucumbers, properly prepared, without taking up any metallic compound other than salt, and preserved in any kind of vinegar, with or without spices; *pickled onions, pickled beets, pickled beans,* and other pickled vegetables are vegetables prepared as described above, and conform in name to the vegetables used.

5. *Salt pickles* are clean, sound, immature cucumbers, preserved in a solution of common salt, with or without spices.

6. *Sweet pickles* are pickled cucumbers or other vegetables in the preparation of which sugar (sucrose) is used.

7. *Sauerkraut* is clean, sound, properly prepared cabbage, mixed with salt, and subjected to fermentation.

8. *Catchup (ketchup, catsup)* is the clean, sound product made from the properly prepared pulp of clean, sound, fresh, ripe tomatoes, with spices and with or without sugar and vinegar; *mushroom catchup, walnut catchup, et cetera,* are catchups made as above described, and conform in name to the substances used in their preparation.

C. SUGARS AND RELATED SUBSTANCES.

a. SUGAR AND SUGAR PRODUCTS.

Sugars.

1. *Sugar* is the product chemically known as sucrose (saccharose) chiefly obtained from sugar cane, sugar beets, sorghum, maple, and palm.

2. *Granulated, loaf, cut, milled,* and *powdered sugars* are different forms of sugar and contain at least ninety-nine and five-tenths (99.5) per cent of sucrose.

[*] Products made with mixtures of sugar, glucose, and honey, or any two thereof, are reserved for future consideration.

3. *Maple sugar* is the solid product resulting from the evaporation of maple sap, and contains, in the water-free substance, not less than sixty-five one-hundredths (0.65) per cent of maple sugar ash.

4. ***Massecuite, melada, mush sugar,*** and *concrete* are products made by evaporating the purified juice of a sugar-producing plant, or a solution of sugar, to a solid or semi-solid consistence, and in which the sugar chiefly exists in a crystalline state.

Molasses and Refiners' Sirup.

1. *Molasses* is the product left after separating the sugar from massecuite, melada, mush sugar, or concrete, and contains not more than twenty-five (25) per cent of water and not more than five (5) per cent of ash.

2. *Refiners' sirup, treacle,* is the residual liquid product obtained in the process of refining raw sugars and contains not more than twenty-five (25) per cent of water and not more than eight (8) per cent of ash.

Sirups.

1. *Sirup* is the sound product made by purifying and evaporating the juice of a sugar-producing plant without removing any of the sugar.

2. *Sugar-cane sirup* is sirup made by the evaporation of the juice of the sugar-cane or by the solution of sugar-cane concrete, and contains not more than thirty (30) per cent of water and not more than two and five-tenths (2.5) per cent of ash.

3. *Sorghum sirup* is sirup made by the evaporation of sorghum juice or by the solution of sorghum concrete, and contains not more than thirty (30) per cent of water and not more than two and five-tenths (2.5) per cent of ash.

4. *Maple sirup* is sirup made by the evaporation of maple sap or by the solution of maple concrete, and contains not more than thirty-two (32) per cent of water and not less than forty-five hundredths (0.45) per cent of maple sirup ash.

5. *Sugar sirup* is the product made by dissolving sugar to the consistence of a sirup and contains not more than thirty-five (35) per cent of water.

b. GLUCOSE PRODUCTS.

1. *Starch sugar* is the solid product made by hydrolyzing starch or a starch-containing substance until the greater part of the starch is converted into dextrose. Starch sugar appears in commerce in two forms, anhydrous starch sugar and hydrous starch sugar. The former, crystallized without water of crystallization, contains not less than ninety-five (95) per cent of dextrose and not more than eight-tenths (0.8) per cent of ash. The latter, crystallized with water of crystallization, is of two varieties—70 sugar, also known as brewers' sugar, contains not less than seventy (70) per cent of dextrose and not more than eight-tenths (0.8) per cent of ash; 80 sugar, climax or acme sugar, contains not less than eighty (80) per cent of dextrose and not more than one and one-half (1.5) per cent of ash.

The ash of all these products consists almost entirely of chlorids and sulphates.

2. *Glucose, mixing glucose, confectioner's glucose,* is a thick, sirupy, colorless product made by incompletely hydrolyzing starch, or a starch-containing substance, and decolorizing and evaporating the product. It varies in density from forty-one (41) to forty-five (45) degrees Baumé at a temperature of 100° Fahr. (37.7° C.), and conforms in density, within these limits, to the degree Baumé it is claimed to show, and for a density of forty-one (41) degrees Baumé contains not more than twenty-one (21) per cent and for a density of forty-five (45) degrees not more than fourteen (14) per cent of water. It contains on a basis of forty-one (41) degrees Baumé not more than one (1) per cent of ash, consisting chiefly of chlorids and sulphates.

c. CANDY.

1. *Candy* is a product made from a saccharine substance or substances with or without the addition of harmless coloring, flavoring, or filling materials and contains no terra alba, barytes, talc, chrome yellow, or other mineral substances, or poisonous colors or flavors, or other ingredients deleterious or detrimental to health, or any vinous, malt, or spirituous liquor or compound, or narcotic drug.

d. HONEY.

1. *Honey* is the nectar and saccharine exudations of plants gathered, modified, and stored in the comb by honey bees (*Apis mellifica* and *A. dorsata*); is lævorotatory, contains not more than twenty-five (25) per cent of water, not more than twenty-five hundredths (0.25) per cent of ash, and not more than eight (8) per cent of sucrose.

2. *Comb honey* is honey contained in the cells of comb.

3. *Extracted honey* is honey which has been separated from the uncrushed comb by centrifugal force or gravity.

4. *Strained honey* is honey removed from the crushed comb by straining or other means.

D. CONDIMENTS (EXCEPT VINEGAR AND SALT).

a. SPICES.

1. *Spices* are aromatic vegetable substances used for the seasoning of food and from which no portion of any volatile oil or other flavoring principle has been removed and which are clean, sound, and true to name.

2. *Allspice, pimento,* is the dried fruit of the *Pimenta pimenta* (L.) Karst., and contains not less than eight (8) per cent of quercitannic acid*; not more than six (6) per cent of total ash, not more than five-tenths (0.5) per cent of ash insoluble in hydrochloric acid, and not more than twenty-five (25) per cent of crude fiber.

3. *Anise* is the fruit of the *Pimpinella anisum* L.

4. *Bay leaf* is the dried leaf of *Laurus nobilis* L.

5. *Capers* are the flower buds of *Capparis spinosa* L.

6. *Caraway* is the fruit of *Carum carvi* L.

Cayenne and Red Peppers.

7. *Red pepper* is the red, dried, ripe fruit of any species of *Capsicum.*

8. *Cayenne pepper, cayenne,* is the dried ripe fruit of *Capsicum frutescens* L., *Capsicum baccatum* L., or some other small-fruited species of *Capsicum,* and contains not less than fifteen (15) per cent of nonvolatile ether extract; not more than six and five-tenths (6.5) per cent of total ash; not more than five-tenths (0.5) per cent of ash insoluble in hydrochloric acid; not more than one and five-tenths (1.5) per cent of starch, and not more than twenty-eight (28) per cent of crude fiber.

9. *Paprika* is the dried ripe fruit of *Capsicum annuum* L., or some other large-fruited species of *Capsicum,* excluding seeds and stems.

10. *Celery seed* is the dried fruit of *Apium graveolens* L.

11. *Cinnamon* is the dried bark of any species of the genus *Cinnamomum* from which the outer layers may or may not have been removed.

12. *True cinnamon* is the dried inner bark of *Cinnamomum zeylanicum* Breyne.

13. *Cassia* is the dried bark of various species of *Cinnamomum,* other than *Cinnamomum zeylanicum,* from which the outer layers may or may not have been removed.

* Calculated from the total oxygen absorbed by the aqueous extract.

14. *Cassia buds* are the dried immature fruit of species of *Cinnamomum*.

15. *Ground cinnamon, ground cassia,* is a powder consisting of cinnamon, cassia, or cassia buds, or a mixture of these spices and contains not more than six (6) per cent of total ash and not more than two (2) per cent of sand.

16. *Cloves* are the dried flower buds of *Caryophyllus aromaticus* L., which contain not more than five (5) per cent of clove stems; not less than ten (10) per cent of volatile ether extract; not less than twelve (12) per cent of quercitannic acid*; not more than eight (8) per cent of total ash; not more than five-tenths (0.5) per cent of ash insoluble in hydrochloric acid, and not more than ten (10) per cent of crude fiber.

17. *Coriander* is the dried fruit of *Coriandrum sativum* L.

18. *Cumin seed* is the fruit of *Cuminum cyminum* L.

19. *Dill seed* is the fruit of *Anethum graveolens* L.

20. *Fennel* is the fruit of *Foeniculum foeniculum* (L.) Karst.

21. *Ginger* is the washed and dried or decorticated and dried rhizome of *Zinziber zingiber* (L.) Karst., and contains not less than forty-two (42) per cent of starch; not more than eight (8) per cent of crude fiber, not more than six (6) per cent of total ash, not more than one (1) per cent of lime, and not more than three (3) per cent of ash insoluble in hydrochloric acid.

22. *Limed ginger, bleached ginger,* is whole ginger coated with carbonate of lime and contains not more than ten (10) per cent of ash, not more than four (4) per cent of carbonate of lime, and conforms in other respects to the standard for ginger.

23. *Horse-radish* is the root of *Roripa armoracia* (L.) Hitchcock, either by itself or ground and mixed with vinegar.

24. *Mace* is the dried arillus of *Myristica fragrans* Houttuyn, and contains not less than twenty (20) nor more than thirty (30) per cent of nonvolatile ether extract, not more than three (3) per cent of total ash, and not more than five-tenths (0.5) per cent of ash insoluble in hydrochloric acid, and not more than ten (10) per cent of crude fiber.

25. *Macassar mace, Papua mace,* is the dried arillus of *Myristica argentea* Warb.

26. *Bombay mace* is the dried arillus of *Myristica malabarica* Lamarck.

27. *Marjoram* is the leaf, flower and branch of *Majorana majorana* (L.) Karst.

28. *Mustard seed* is the seed of *Sinapis alba* L. (white mustard), *Brassica nigra* (L.) Koch (black mustard), or *Brassica juncea* (L.) Cosson (black or brown mustard).

29. *Ground mustard* is a powder made from mustard seed, with or without the removal of the hulls and a portion of the fixed oil, and contains not more than two and five-tenths (2.5) per cent of starch and not more than eight (8) per cent of total ash.

30. *Prepared mustard, German mustard, French mustard, mustard paste,* is a paste composed of a mixture of ground mustard seed or mustard flour with salt, spices and vinegar, and, calculated free from water, fat and salt, contains not more than twenty-four (24) per cent of carbohydrates, calculated as starch, determined according to the official methods, not more than twelve (12) per cent of crude fiber nor less than thirty-five (35) per cent of protein, derived solely from the materials named.

31. *Nutmeg* is the dried seed of the *Myristica fragrans* Houttuyn, deprived of its testa, with or without a thin coating of lime, and contains not less than twenty-five (25) per cent of nonvolatile ether extract, not more than five (5) per cent

* Calculated from the total oxygen absorbed by the aqueous extract.

of total ash, not more than five-tenths (0.5) per cent of ash insoluble in hydrochloric acid, and not more than ten (10) per cent of crude fiber.

32. *Macassar nutmeg, Papua nutmeg, male nutmeg, long nutmeg,* is the dried seed of *Myristica argentea* Warb. deprived of its testa.

Pepper.

33. *Black pepper* is the dried immature berry of *Piper nigrum* L. and contains not less than six (6) per cent of nonvolatile ether extract, not less than twenty-five (25) per cent of starch, not more than seven (7) per cent of total ash, not more than two (2) per cent of ash insoluble in hydrochloric acid, and not more than fifteen (15) per cent of crude fiber. One hundred parts of the nonvolatile ether extract contain not less than three and one-quarter (3.25) parts of nitrogen. *Ground black pepper* is the product made by grinding the entire berry and contains the several parts of the berry in their normal proportions.

34. *Long pepper* is the dried fruit of *Piper longum* L.

35. *White pepper* is the dried mature berry of *Piper nigrum* L. from which the outer coating or the outer and inner coatings have been removed and contains not less than six (6) per cent of nonvolatile ether extract, not less than fifty (50) per cent of starch, not more than four (4) per cent of total ash, not more than five-tenths (0.5) per cent of ash insoluble in hydrochloric acid, and not more than five (5) per cent of crude fiber. One hundred parts of the nonvolatile ether extract contain not less than four (4) parts of nitrogen.

36. *Saffron* is the dried stigma of *Crocus sativus* L.

37. *Sage* is the leaf of *Salvia officinalis* L.

38. *Savory, summer savory,* is the leaf, blossom, and branch of *Satureja hortensis* L.

39. *Thyme* is the leaf and tip of blooming branches of *Thymus vulgaris* L.

b. FLAVORING EXTRACTS.

1. *A flavoring extract* * is a solution in ethyl alcohol of proper strength of the sapid and odorous principles derived from an aromatic plant, or parts of the plant, with or without its coloring matter, and conforms in name to the plant used in its preparation.

2. *Almond extract* is the flavoring extract prepared from oil of bitter almonds, free from hydrocyanic acid, and contains not less than one (1) per cent by volume of oil of bitter almonds.

2a. *Oil of bitter almonds,* commercial, is the volatile oil obtained from the seed of the bitter almond (*Amygdalus communis* L.), the apricot (*Prunus armeniaca* L.), or the peach (*Amygdalus persica* L.).

3. *Anise extract* is the flavoring extract prepared from oil of anise, and contains not less than three (3) per cent by volume of oil of anise.

3a. *Oil of anise* is the volatile oil obtained from the anise seed.

4. *Celery seed extract* is the flavoring extract prepared from celery seed or the oil of celery seed, or both, and contains not less than three-tenths (0.3) per cent by volume of oil of celery seed.

4a. *Oil of celery seed* is the volatile oil obtained from celery seed.

5. *Cassia extract* is the flavoring extract prepared from oil of cassia and contains not less than two (2) per cent by volume of oil of cassia.

5a. *Oil of cassia* is the lead-free volatile oil obtained from the leaves or bark of *Cinnamomum cassia* Bl., and contains not less than seventy-five (75) per cent by weight of cinnamic aldehyde.

* The flavoring extracts herein described are intended solely for food purposes and are not to be confounded with similar preparations described in the Pharmacopeia for medicinal purposes.

6. *Cinnamon extract* is the flavoring extract prepared from oil of cinnamon, and contains not less than two (2) per cent by volume of oil of cinnamon.

6*a*. *Oil of cinnamon* is the lead-free volatile oil obtained from the bark of the Ceylon cinnamon (*Cinnamomum zeylanicum* Breyne), and contains not less than sixty-five (65) per cent by weight of cinnamic aldehyde and not more than ten (10) per cent by weight of eugenol.

7. *Clove extract* is the flavoring extract prepared from oil of cloves, and contains not less than two (2) per cent by volume of oil of cloves.

7*a*. *Oil of cloves* is the lead-free, volatile oil obtained from cloves.

8. *Ginger extract* is the flavoring extract prepared from ginger and contains in each one hundred (100) cubic centimeters, the alcohol-soluble matters from not less than twenty (20) grams of ginger.

9. *Lemon extract* is the flavoring extract prepared from oil of lemon, or from lemon peel, or both, and contains not less than five (5) per cent by volume of oil of lemon.

9*a*. *Oil of lemon* is the volatile oil obtained, by expression or alcoholic solution, from the fresh peel of the lemon (*Citrus limonum* L.), has an optical rotation (25° C.) of not less than +60° in a 100-millimeter tube, and contains not less than four (4) per cent by weight of citral.

10. *Terpeneless extract of lemon* is the flavoring extract prepared by shaking oil of lemon with dilute alcohol, or by dissolving terpeneless oil of lemon in dilute alcohol, and contains not less than two-tenths (0.2) per cent by weight of citral derived from oil of lemon.

10*a*. *Terpeneless oil of lemon* is oil of lemon from which all or nearly all of the terpenes have been removed.

11. *Nutmeg extract* is the flavoring extract prepared from oil of nutmeg, and contains not less than two (2) per cent by volume of oil of nutmeg.

11*a*. *Oil of nutmeg* is the volatile oil obtained from nutmegs.

12. *Orange extract* is the flavoring extract prepared from oil of orange, or from orange peel, or both, and contains not less than five (5) per cent by volume of oil of orange.

12*a*. *Oil of orange* is the volatile oil obtained, by expression or alcoholic solution, from the fresh peel of the orange (*Citrus aurantium* L.) and has an optical rotation (25° C.) of not less than +95° in a 100-millimeter tube.

13. *Terpeneless extract of orange* is the flavoring extract prepared by shaking oil of orange with dilute alcohol, or by dissolving terpeneless oil of orange in dilute alcohol, and corresponds in flavoring strength to orange extract.

13*a*. *Terpeneless oil of orange* is oil of orange from which all or nearly all of the terpenes have been removed.

14. *Peppermint extract* is the flavoring extract prepared from oil of peppermint, or from peppermint, or both, and contains not less than three (3) per cent by volume of oil of peppermint.

14*a*. *Peppermint* is the leaves and flowering tops of *Mentha piperita* L.

14*b*. *Oil of peppermint* is the volatile oil obtained from peppermint and contains not less than fifty (50) per cent by weight of menthol.

15. *Rose extract* is the flavoring extract prepared from otto of roses, with or without red rose petals, and contains not less than four-tenths (0.4) per cent by volume of otto of roses.

15*a*. *Otto of roses* is the volatile oil obtained from the petals of *Rosa damascena* Mill., *R. centifolia* L., or *R. moschata* Herrm.

16. *Savory extract* is the flavoring extract prepared from oil of savory, or from savory, or both, and contains not less than thirty-five hundredths (0.35) per cent by volume of oil of savory.

16*a*. *Oil of savory* is the volatile oil obtained from savory.

17. *Spearmint extract* is the flavoring extract prepared from oil of spearmint, or from spearmint, or both, and contains not less than three (3) per cent by volume of oil of spearmint.

17*a*. *Spearmint* is the leaves and flowering tops of *Mentha spicata* L.

17*b*. *Oil of spearmint* is the volatile oil obtained from spearmint.

18. *Star anise extract* is the flavoring extract prepared from oil of star anise, and contains not less than three (3) per cent by volume of oil of star anise.

18*a*. *Oil of star anise* is the volatile oil distilled from the fruit of the star anise (*Illicium verum* Hook).

19. *Sweet basil extract* is the flavoring extract prepared from oil of sweet basil, or from sweet basil, or both, and contains not less than one-tenth (0.1) per cent by volume of oil of sweet basil.

19*a*. *Sweet basil, basil,* is the leaves and tops of *Ocymum basilicum* L.

19*b*. *Oil of sweet basil* is the volatile oil obtained from basil.

20. *Sweet marjoram extract, marjoram extract,* is the flavoring extract prepared from the oil of marjoram, or from marjoram, or both, and contains not less than one (1) per cent by volume of oil of marjoram.

20*a*. *Oil of marjoram* is the volatile oil obtained from marjoram.

21. *Thyme extract* is the flavoring extract prepared from oil of thyme, or from thyme, or both, and contains not less than two-tenths (0.2) per cent by volume of oil of thyme.

21*a*. *Oil of thyme* is the volatile oil obtained from thyme.

22. *Tonka extract* is the flavoring extract prepared from tonka bean, with or without sugar or glycerin, and contains not less than one-tenth (0.1) per cent by weight of coumarin extracted from the tonka bean, together with a corresponding proportion of the other soluble matters thereof.

22*a*. *Tonka bean* is the seed of *Coumarouna odorata* Aublet (*Dipteryx odorata* (Aubl.) Willd.).

23. *Vanilla extract* is the flavoring extract prepared from vanilla bean, with or without sugar or glycerin, and contains in one hundred (100) cubic centimeters the soluble matters from not less than ten (10) grams of the vanilla bean.

23*a*. *Vanilla bean* is the dried, cured fruit of *Vanilla planifolia* Andrews.

24. *Wintergreen extract* is the flavoring extract prepared from oil of wintergreen, and contains not less than three (3) per cent by volume of oil of wintergreen.

24*a*. *Oil of wintergreen* is the volatile oil distilled from the leaves of the *Gaultheria procumbens* L.

C. EDIBLE VEGETABLE OILS AND FATS.

1. *Olive oil* is the oil obtained from the sound, mature fruit of the cultivated olive tree (*Olea europoea* L.) and subjected to the usual refining processes; is free from rancidity; has a refractive index (25° C.) not less than one and forty-six hundred and sixty ten-thousandths (1.4660) and not exceeding one and forty-six hundred and eighty ten-thousandths (1.4680); and an iodin number not less than seventy-nine (79) and not exceeding ninety (90).

2. *Virgin olive oil* is olive oil obtained from the first pressing of carefully selected, hand-picked olives.

3. *Cotton-seed oil* is the oil obtained from the seeds of cotton plants (*Gossypium hirsutum* L., *G. barbadense* L., or *G. herbaceum* L.) anud subjected to the usual refining processes; is free from rancidity, has a refractive index (25° C.) not less than one and forty-seven hundred ten-thousandths (1.4700) and not exceeding one and forty-seven hundred and twenty-five ten-thousandths (1.4725); and an iodin number not less than one hundred and four (104) and not exceeding one hundred and ten (110).

4. *"Winter-yellow" cotton-seed oil* is expressed cotton-seed oil from which a portion of the stearin has been separated by chilling and pressure, and has an iodin number not less than one hundred and ten (110) and not exceeding one hundred and sixteen (116).

5. *Peanut oil, arachis oil, earthnut oil,* is the oil obtained from the peanut (*Arachis hypoglig* L.) and subjected to the usual refining processes; is free from rancidity; has a refractive index (25° C.) not less than one and forty-six hundred and ninety ten-thousandths (1.4690) and not exceeding one and forty-seven hundred and seven ten thousandths (1.4707); and an iodin number not less than eighty-seven (87) and not exceeding one hundred (100).

6. *"Cold-drawn" peanut oil* * is peanut oil obtained by pressure without heating.

7. *Sesame oil, gingili oil, teel oil,* is the oil obtained from the seeds of the sesame plants (*Sesamum orientale* L. and *S. radiatum* Schum. and Thonn.) and subjected to the usual refining processes; is free from rancidity; has a refractive index (25° C.) not less than one and forty-seven hundred and four ten-thousandths (1.4704) and not exceeding one and forty-seven hundred and seventeen ten-thousandths (1.4717); and an iodin number not less than one hundred and three (103) and not exceeding one hundred and twelve (112).

8. *"Cold-drawn" sesame oil* * is sesame oil obtained by pressure without heating.

9. *Poppy-seed oil* * is the oil obtained from the seed of the poppy (*Papaver somniferum* L.) subjected to the usual refining processes and free from rancidity.

10. *White poppy-seed oil, "cold-drawn" poppy-seed oil,** is poppy-seed oil of the first pressing without heating.

11. *Coconut oil* * is the oil obtained from the kernels of the coconut (*Cocos nucifera* L.) and subjected to the usual refining processes and free from rancidity.

12. *Cochin oil* is coconut oil prepared in Cochin (Malabar).

13. *Ceylon oil* is coconut oil prepared in Ceylon.

14. *Copra oil* is coconut oil prepared from copra, the dried kernels of the coconut.

15. *Rape-seed oil, colza oil,** is the oil obtained from the seeds of the rape plant (*Brassica napus* L.) and subjected to the usual refining processes and free from rancidity.

16. *"Cold-drawn" rape-seed oil* * is rape-seed oil obtained by the first pressing without heating.

17. *Sunflower oil* * is the oil obtained from the seeds of the sunflower (*Helianthus annuus* L.) and subjected to the usual refining processes and free from rancidity.

18. *"Cold-drawn" sunflower oil* * is sunflower oil obtained by the first pressing without heating.

19. *Maize oil, corn oil,** is the oil obtained from the germ of the maize (*Zea mays* L.) and subjected to the usual refining processes and free from rancidity.

* **The fixing of limits for chemical and physical properties is reserved for future consideration.**

20. *Cocoa butter, cacao butter,* is the fat obtained from roasted, sound cocoa beans, and subjected to the usual refining processes; is free from rancidity; has a refractive index (40° C.) not less than one and forty-five hundred and sixty six ten-thousandths (1.4566) and not exceeding one and forty-five hundred and ninety-eight ten-thousandths (1.4598), an iodin number not less than thirty-three (33) and not exceeding thirty-eight (38); and a melting point not lower than 30° C. nor higher than 35° C.

21. *Cotton-seed oil stearin* is the solid product made by chilling cotton-seed oil and separating the solid portion by filtration, with or without pressure, and having an iodin number not less than eighty-five (85) and not more than one hundred (100).

E. Tea, Coffee, and Cocoa Products.

a. TEA.

1. *Tea* is the leaves and leaf buds of different species of *Thea,* prepared by the usual trade processes of fermenting, drying, and firing; meets the provisions of the act of Congress approved March 2, 1897, and the regulations made in conformity therewith (Treasury Department Circular 16, February 6, 1905); conforms in variety and place of production to the name it bears; and contains not less than four (4) nor more than seven (7) per cent of ash.

b. COFFEE.

1. *Coffee* is the seed of *Coffea arabica* L. or *Coffea liberica* Bull., freed from all but a small portion of its spermoderm, and conforms in variety and place of production to the name it bears.

2. *Roasted coffee* is coffee which by the action of heat has become brown and developed its characteristic aroma, and contains not less than ten (10) per cent of fat and not less than three (3) per cent of ash.

c. COCOA AND COCOA PRODUCTS.

1. *Cocoa beans* are the seeds of the cacao tree, *Theobroma cacao* L.

2. *Cocoa nibs, cracked cocoa,* is the roasted, broken cocoa bean freed from its shell or husk.

3. *Chocolate, plain chocolate, bitter chocolate, chocolate liquor, bitter chocolate coatings,* is the solid or plastic mass obtained by grinding cocoa nibs without the removal of fat or other constituents except the germ, and contains not more than three (3) per cent of ash insoluble in water, three and fifty hundredths (3.50) per cent of crude fiber, and nine (9) per cent of starch, and not less than forty-five (45) per cent of cocoa fat.

4. *Sweet chocolate, sweet chocolate coatings,* is chocolate mixed with sugar (sucrose), with or without the addition of cocoa butter, spices, or other flavoring materials, and contains in the sugar- and fat-free residue no higher percentage of either ash, fiber, or starch than is found in the sugar- and fat-free residue of chocolate.

5. *Cocoa, powdered cocoa,* is cocoa nibs, with or without the germ, deprived of a portion of its fat and finely pulverized, and contains percentages of ash, crude fiber, and starch corresponding to those in chocolate after correction for fat removed.

6. *Sweet cocoa, sweetened cocoa,* is cocoa mixed with sugar (sucrose), and contains not more than sixty (60) per cent of sugar (sucrose), and in the sugar- and fat-free residue no higher percentage of either ash, crude fiber, or starch than is found in the sugar- and fat-free residue of chocolate.

F. Beverages.

a. Fruit Juices—Fresh, Sweet, and Fermented.

1. Fresh and 2. Sweet.

(Schedules in preparation.)

3. Fermented Fruit Juices.

1. *Wine* is the product made by the normal alcoholic fermentation of the juice of sound, ripe grapes, and the usual cellar treatment,* and contains not less than seven (7) nor more than sixteen (16) per cent of alcohol, by volume, and, in one hundred (100) cubic centimeters (20° C.), not more than one-tenth (0.1) gram of sodium chlorid nor more than two-tenths (0.2) gram of potassium sulphate; and for red wine not more than fourteen hundredths (0.14) gram, and for white wine not more than twelve hundredths (0.12) gram of volatile acids produced by fermentation and calculated as acetic acid. *Red wine* is wine containing the red coloring matter of the skins of grapes. *White wine* is wine made from white grapes or the expressed fresh juice of other grapes.

2. *Dry wine* is wine in which the fermentation of the sugars is practically complete and which contains, in one hundred (100) cubic centimeters (20° C.), less than one (1) gram of sugars and for dry red wine not less than sixteen hundredths (0.16) gram of grape ash and not less than one and six-tenths (1.6) grams of sugar-free grape solids, and for dry white wine not less than thirteen hundredths (0.13) gram of grape ash and not less than one and four-tenths (1.4) grams of sugar-free grape solids.

3. *Fortified dry wine* is dry wine to which brandy has been added but which conforms in all other particulars to the standard of dry wine.

4. *Sweet wine* is wine in which the alcoholic fermentation has been arrested, and which contains, in one hundred (100) cubic centimeters (20° C.), not less than one (1) gram of sugars, and for sweet red wine not less than sixteen hundredths (0.16) gram of grape ash, and for sweet white wine not less than thirteen hundredths (0.13) gram of grape ash.

5. *Fortified sweet wine* is sweet wine to which wine spirits have been added. By act of Congress, "sweet wine" used for making fortified sweet wine and "wine spirits" used for such fortification are defined as follows (sec. 43, Act of October 1, 1890, 26 Stat., 567, as amended by section 68, Act of August 27, 1894, 28 Stat., 509, and further amended by Act of Congress approved June 7, 1906): "That the wine spirits mentioned in section 42 of this act is the product resulting from the distillation of fermented grape juice to which water may have been added prior to, during, or after fermentation, for the sole purpose of facilitating the fermentation and economical distillation thereof, and shall be held to include the products from grapes or their residues, commonly known as grape brandy; and the pure sweet wine, which may be fortified free of tax, as provided in said section, is fermented grape juice only, and shall contain no other substance whatever introduced before, at the time of, or after fermentation, except as herein expressly provided; and such sweet wine shall contain not less than four per centum of saccharine matter, which saccharine strength may be determined by testing with Balling's saccharometer or must scale, such sweet wine, after the evaporation of the spirits contained therein, and restoring the sample tested to original volume by addition of water: *Provided*, That the addition of pure boiled or condensed grape must or pure crystallized cane or beet sugar or pure anhydrous sugar to the pure grape juice aforesaid, or the fermented product of such grape juice prior to the fortification provided by this Act for the sole purpose of perfecting sweet

* The subject of sulphurous acid in wine is reserved for consideration in connection with the schedule, "Preservatives and Coloring Matters."

wine according to commercial standard, or the addition of water in such quantities only as may be necessary in the mechanical operation of grape conveyors, crushers, and pipes leading to fermenting tanks, shall not be excluded by the definition of pure sweet wine aforesaid: *Provided, however,* That the cane or beet sugar, or pure anhydrous sugar, or water, so used shall not in either case be in excess of ten (10) per centum of the weight of the wine to be fortified under this Act: *And provided further,* That the addition of water herein authorized shall be under such regulations and limitations as the Commissioner of Internal Revenue, with the approval of the Secretary of the Treasury, may from time to time prescribe; but in no case shall such wines to which water has been added be eligible for fortification under the provisions of this Act where the same, after fermentation and before fortification, have an alcoholic strength of less than five per centum of their volume."

6. *Sparkling wine* is wine in which the after part of the fermentation is completed in the bottle, the sediment being disgorged and its place supplied by wine or sugar liquor, and which contains, in one hundred (100) cubic centimeters (20° C.), not less than twelve hundredths (0.12) gram of grape ash.

7. *Modified wine, ameliorated wine, corrected wine,* is the product made by the alcoholic fermentation, with the usual cellar treatment, of a mixture of the juice of sound, ripe grapes with sugar (sucrose), or a sirup containing not less than sixty-five (65) per cent of sugar (sucrose), and in quantity not more than enough to raise the alcoholic strength after fermentation, to eleven (11) per cent by volume.

8. *Raisin wine* is the product made by the alcoholic fermentation of an infusion of dried or evaporated grapes, or of a mixture of such infusion or of raisins with grape juice.

b. MEAD, ROOT BEER, ETC.

(Schedule in preparation.)

c. MALT LIQUORS.

(Schedule in preparation.)

d. SPIRITUOUS LIQUORS.

(Schedule in preparation.)

e. CARBONATED WATERS, ETC.

(Schedule in preparation.)

G. VINEGAR.

1. *Vinegar, cider vinegar, apple vinegar,* is the product made by the alcoholic and subsequent acetous fermentations of the juice of apples, is lævo-rotatory, and contains not less than four (4) grams of acetic acid, not less than one and six-tenths (1.6) grams of apple solids, of which not more than fifty (50) per cent are reducing sugars, and not less than twenty-five hundredths (0.25) gram of apple ash in one hundred (100) cubic centimeters (20° C.); and the water-soluble ash from one hundred (100) cubic centimeters (20° C.) of the vinegar contains not less than ten (10) milligrams of phosphoric acid (P_2O_5), and requires not less than thirty (30) cubic centimeters of decinormal acid to neutralize its alkalinity.

2. *Wine vinegar, grape vinegar,* is the product made by the alcoholic and subsequent acetous fermentations of the juice of grapes and contains, in one hundred (100) cubic centimeters (20° C.), not less than four (4) grams of acetic acid, not less than one (1.0) gram of grape solids, and not less than thirteen hundredths (0.13) gram of grape ash.

3. *Malt vinegar* is the product made by the alcoholic and subsequent acetous fermentations, without distillation, of an infusion of barley malt or cereals whose

starch has been converted by malt, is dextro-rotatory, and contains, in one hundred (100) cubic centimeters (20° C.), not less than four (4) grams of acetic acid, not less than two (2) grams of solids, and not less than two-tenths (0.2) gram of ash; and the water-soluble ash from one hundred (100) cubic centimeters (20° C.) of the vinegar contains not less than nine (9) milligrams of phosphoric acid (P_2O_5), and requires not less than four (4) cubic centimeters of decinormal acid to neutralize its alkalinity.

4. *Sugar vinegar* is the product made by the alcoholic and subsequent acetous fermentations of solutions of sugar, sirup, molasses, or refiners' sirup, and contains, in one hundred (100) cubic centimeters (20° C.), not less than four (4) grams of acetic acid.

5. *Glucose vinegar* is the product made by the alcoholic and subsequent acetous fermentations of solutions of starch sugar or glucose, is dextro-rotatory, and contains, in one hundred (100) cubic centimeters (20° C.), not less than four (4) grams of acetic acid.

6. *Spirit vinegar, distilled vinegar, grain vinegar,* is the product made by the acetous fermentation of dilute distilled alcohol, and contains, in one hundred (100) cubic centimeters (20° C.), not less than four (4) grams of acetic acid.

III. SALT.

1. *Table salt, dairy salt,* is fine-grained crystalline salt containing on a water-free basis, not more than one and four-tenths (1.4) per cent of calcium sulphate ($CaSO_4$), nor more than five-tenths (0.5) per cent of calcium and magnesium chlorids ($CaCl_2$ and $MgCl_2$), nor more than one-tenth (0.1) per cent of matters insoluble in water.

IV. PRESERVATIVES AND COLORING MATTERS.
(Schedules in preparation.)

Annex B *

S. R. A., F. D. No. 2, Rev. 5 Issued November 1936

UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD AND DRUG ADMINISTRATION

Service and Regulatory Announcements

Food and Drug No. 2

(Fifth Revision)

Definitions and Standards for Food Products for Use in Enforcing the Food and Drugs Act

The following definitions and standards for food products have been adopted as a guide for the officials of this Department in enforcing the Food and Drugs Act. These are standards of identity and are not to be confused with standards of quality or grade; they are so framed as to exclude substances not mentioned in the definition and in each instance imply that the product is clean and sound. These definitions and standards include those published in S. R. A., F. D. 2, revision 4, and those adopted October 28, 1936.

H. A. WALLACE, *Secretary of Agriculture.*

WASHINGTON, D. C., *November 5, 1936.*

* [Editor's Note: Annex B contains the food standards officially used in the administration of the original Federal Food and Drugs Act, as they were last revised thereunder and published by the United States Department of Agriculture in Food and Drug No. 2, Fifth Revision, on November 5, 1936. These food standards have been superseded by those legally established under the succeeding Federal Food, Drug, and Cosmetic Act of 1938.]

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ANIMAL PRODUCTS

MEATS AND THE PRINCIPAL MEAT PRODUCTS

A. MEATS

1. FLESH. Any edible part of the striated muscle of an animal. The term "animal", as herein used, indicates a mammal, a fowl, a fish, a crustacean, a mollusk, or any other animal used as a source of food.

2. MEAT.[1] The properly dressed flesh derived from cattle, from swine, from sheep, or from goats, sufficiently mature and in good health at the time of

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slaughter, but restricted to that part of the striated muscle which is skeletal or that which is found in the tongue, in the diaphragm, in the heart, or in the esophagus, and does not include that found in the lips, in the snout, or in the ears, with or without the accompanying and overlying fat, and the portions of bone, skin, sinew, nerve, and blood vessels which normally accompany the flesh and which may not have been separated from it in the process of dressing it for sale.

3. FRESH MEAT. Meat which has undergone no substantial change in character since the time of slaughter.

4. BEEF. Meat derived from cattle nearly 1 year of age or older.

5. VEAL. Meat derived from young cattle 1 year or less of age.[2]

6. MUTTON. Meat derived from sheep nearly 1 year of age or older.

7. LAMB. Meat derived from young sheep 1 year or less of age.[2]

8. PORK. Meat derived from swine.

9. VENISON. Flesh derived from deer.

B. MEAT BYPRODUCTS

MEAT BYPRODUCTS. Any properly dressed edible parts, other than meat, which have been derived from one or more carcasses of cattle, of swine, of sheep, or of goats, sufficiently mature and in good health at the time of slaughter.

C. PREPARED MEATS

1. PREPARED MEAT. The product obtained by subjecting meat to a process of comminuting, of drying, of curing, and smoking, of cooking, of seasoning, or of flavoring, or to any combination of such processes.

2. CURED MEAT. The product obtained by subjecting meat to a process of salting, by the employment of dry common salt or of brine, with or without the use of one or more of the following: Sodium nitrite, sodium nitrate, potassium nitrate, sugar, dextrose, a sirup, honey, spice.

3. DRY SALT MEAT. The prepared meat, which has been cured by the application of dry common salt, with or without the use of one or more of the following: Sodium nitrite, sodium nitrate, potassium nitrate, sugar, dextrose, a sirup, honey, spice; with or without the injection into it of a solution of common salt to which may have been added one or more of the following: Sodium nitrite, sodium nitrate, potassium nitrate, sugar, dextrose, a sirup, honey.

4. CORNED MEAT. The prepared meat which has been cured by soaking in, with or without injecting into it, a solution of common salt, with or without

[1] The term "meat" when used in a qualified form, as, for example, "horse meat," "reindeer meat," "crab meat," etc., is then, and then only, properly applied to corresponding portions of animals other than cattle, swine, sheep, and goats.

[2] Minimum limits governing the age or the weight or both of these have been fixed by certain States and municipalities in the case of calves and lambs to be slaughtered for meat.

one or more of the following, each in its proper proportion: Sodium nitrite, sodium nitrate, potassium nitrate, sugar, dextrose, a sirup, honey, and with or without the use of spice.

5. SWEET PICKLED MEAT. The prepared meat which has been cured by soaking in, with or without injecting into it, a solution of common salt, with sugar and/or dextrose, a sirup, and/or honey, together with one or more of the following, each in its proper proportion: Sodium nitrite, sodium nitrate, potassium nitrate, and with or without the use of spice.

6. DRIED MEAT. The product obtained by subjecting fresh meat or cured meat to a process of drying, with or without the aid of artificial heat, until a substantial portion of the water has been removed.

7. SMOKED MEAT. The product obtained by subjecting fresh meat, dried meat, or cured meat to the direct action of the smoke either of burning wood or of similar burning material.

8. CANNED MEAT. Fresh meat or prepared meat, packed in hermetically sealed containers, with or without subsequent heating for the purpose of sterilization.

9. HAMBURG STEAK, "HAMBURGER STEAK." Comminuted fresh beef, with or without addition of suet, and/or of seasoning.

10. POTTED MEAT, DEVILED MEAT. The product obtained by comminuting and cooking fresh meat and/or prepared meat, with or without spice. It is usually packed in hermetically sealed containers.

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11. SAUSAGE MEAT. Fresh meat or prepared meat, or a mixture of fresh meat and prepared meat. It is sometimes comminuted. The term "sausage meat" is sometimes applied to bulk sausage containing no meat byproducts.

D. MEAT FOOD PRODUCTS

1. MEAT FOOD PRODUCTS. Any articles of food or any articles that enter into the composition of food which are not prepared meats but which are derived or prepared, in whole or in part, by a process of manufacture from any portion of the carcasses of cattle, swine, sheep, or goats, if such manufactured portion be all, or a considerable and definite portion of the articles, except such preparations as are for medicinal purposes only.

2. MEAT LOAF. The product consisting of a mixture of comminuted meat with spice and/or with cereals, with or without milk and/or eggs, pressed into the form of a loaf and cooked.

3. PORK SAUSAGE. Chopped or ground fresh pork, with or without one or more of the following: Herbs, spice, common salt, sugar, dextrose, a sirup, water.

4. BRAWN. The product made from chopped or ground and cooked edible parts of swine, chiefly from the head, feet, and/or legs, with or without the chopped or ground tongue.

5. HEADCHEESE, MOCK BRAWN. The product made from chopped or ground, cooked edible parts of meat or meat byproducts.

6. SOUSE. The product consisting of meat and/or meat byproducts; after cooking, the mixture is commonly packed into containers and covered with vinegar.

7. SCRAPPLE. The product consisting of meat and/or meat byproducts mixed with meal or the flour of grain, and cooked with seasoning materials, after which it is poured into a mold.

E. LARD

1. LARD. The rendered fresh fat from hogs in good health at the time of slaughter. It is free from rancidity, and contains, necessarily incorporated in the process of rendering, not more than 1 percent of substances other than fatty acids and fat.

2. LEAF LARD. Lard rendered at moderately high temperatures from the internal fat of the abdomen of the hog, excluding that adherent to the intestines, and having an iodine number not greater than 60.

3. NEUTRAL LARD. Lard rendered at low temperatures.

Eggs and Egg Products

1. LIQUID EGGS, MIXED EGGS. The product obtained by separating the edible portion of eggs from the shells. It is an intimate mixture of the whites and yolks in their natural proportions.

2. FROZEN EGGS. The solidified product obtained by quickly and completely freezing liquid eggs.

3. DRIED EGGS. The product obtained by evaporating the water from liquid eggs. It contains not more than 7 per cent of moisture.

4. EGG YOLK. The product obtained by removing the whites from the yolks in the commercial process of egg-breaking. It contains not more than 12 per cent by weight of adhering white.

5. FROZEN EGG YOLK. The solidified product obtained by quickly and completely freezing egg yolk.

6. DRIED EGG YOLK. The product obtained by evaporating the water from egg yolk. It contains not more than 5 per cent of moisture.

Milk and Milk Products

A. MILKS

1. MILK. The whole, fresh lacteal secretion obtained by the complete milking of one or more healthy cows, excluding that obtained within 15 days before and 5 days after calving, or such longer period as may be necessary to render the milk practically colostrum-free. The name "milk" unqualified means cow's milk.

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2. PASTEURIZED MILK. Milk every particle of which has been subjected to a temperature not lower than 142° F. for not less than 30 minutes and then promptly cooled to 50° F. or lower.

3. HOMOGENIZED MILK. Milk that has been mechanically treated in such a manner as to alter its physical properties, with particular reference to the condition and appearance of the fat globules.

4. EVAPORATED MILK. The product resulting from the evaporation of a considerable portion of the water from milk, or from milk with adjustment, if necessary, of the ratio of fat to nonfat solids by the addition or by the abstraction of cream. It contains not less than 7.8 per cent of milk fat, nor less than 25.5 per cent of total milk solids; provided, however, that the sum of the percentages of milk fat and total milk solids be not less than 33.7.

5. SWEETENED CONDENSED MILK. The product resulting from the evaporation of a considerable portion of the water from milk to which sugar and/or dextrose has been added. It contains not less than 28 per cent of total milk solids, and not less than 8 per cent of milk fat.

6. DRIED MILK. The product resulting from the removal of water from milk. It contains not less than 26 per cent of milk fat and not more than 5 per cent of moisture.

7. MALTED MILK. The product made by combining whole milk with the liquid separated from a mash of ground barley malt and wheat flour, with or without the addition of sodium chloride, sodium bicarbonate, and potassium bicarbonate, in such a manner as to secure the full enzymic action of the malt extract, and by removing water. The resulting product contains not less than 7.5 per cent of butterfat and not more than 3.5 per cent of moisture.

8. GOAT'S MILK and EWE'S MILK. The whole, fresh lacteal secretions free from colostrum obtained by the complete milking of the healthy animals. The milk conforms in name to the species of animal from which it is obtained.

B. SKIM MILKS

1. SKIM MILK, SKIMMED MILK. That portion of milk which remains after removal of the cream in whole or in part.

2. EVAPORATED SKIMMED MILK. The product resulting from the evaporation of a considerable portion of the water from skimmed milk. It contains not less than 20 per cent of milk solids.

3. SWEETENED CONDENSED SKIMMED MILK. The product resulting from the evaporation of a considerable portion of the water from skimmed milk to which sugar and/or dextrose has been added. It contains not less than 24 per cent of milk solids.

4. DRIED SKIMMED MILK. The product resulting from the removal of water from skimmed milk. It contains not more than 5 per cent of moisture.

5. BUTTERMILK. The product that remains when fat is removed from milk or cream, sweet or sour, in the process of churning. It contains not less than 8.5 per cent of milk solids not fat.

6. CULTURED BUTTERMILK. The product obtained by souring pasteurized skimmed or partially skimmed milk by means of a suitable culture of lactic bacteria. It contains not less than 8.5 per cent of milk solids not fat.

C. CREAM

1. CREAM, SWEET CREAM. That portion of milk, rich in milk fat, which rises to the surface of milk on standing or is separated from it by centrifugal force. It contains not less than 18 per cent of milk fat and not more than 0.2 per cent of acid-reacting substances, calculated in terms of lactic acid.

2. WHIPPING CREAM. Cream which contains not less than 30 per cent of milk fat.

3. HOMOGENIZED CREAM. Cream that has been mechanically treated in such a manner as to alter its physical properties, with particular reference to the condition and appearance of the fat globules.

D. MILK FAT OR BUTTERFAT

MILK FAT, BUTTERFAT. The fat of milk.

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E. BUTTER

BUTTER. The food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter. It contains not less than 80 per cent by weight of milk fat, all tolerances having been allowed for.[3]

[3] In conformity with act of Congress approved Mar. 4, 1923.

F. CHEESE

1. CHEESE.[4] The product made from the separated curd obtained by coagulating the casein of milk, skimmed milk, or milk enriched with cream. The coagulation is accomplished by means of rennet or other suitable enzyme, lactic fermentation, or by a combination of the two. The curd may be modified by heat, pressure, ripening ferments, special molds, or suitable seasoning.

Certain varieties of cheese are made from the milk of animals other than the cow.

The name "cheese" unqualified means Cheddar cheese (American cheese, American Cheddar cheese).

Whole Milk Cheese

2. CHEDDAR CHEESE, AMERICAN CHEESE, AMERICAN CHEDDAR CHEESE. The cheese made by the Cheddar process from heated and pressed curd obtained by the action of rennet on whole milk. It contains not more than 39 per cent of water, and, in the water-free substance, not less than 50 per cent of milk fat.

3. PINEAPPLE CHEESE. The cheese made by the pineapple Cheddar cheese process from pressed curd obtained by the action of rennet on whole milk. The curd is formed into a shape resembling a pineapple, with characteristic surface corrugations, and during the ripening period the cheese is thoroughly coated and rubbed with a suitable oil, with or without shellac. The finished cheese contains, in the water-free substance, not less than 50 per cent of milk fat.

4. LIMBURGER CHEESE. The cheese made by the Limburger process from unpressed curd obtained by the action of rennet on whole milk. The curd is ripened in a damp atmosphere by special fermentation. The finished cheese contains, in the water-free substance, not less than 50 per cent of milk fat.

5. BRICK CHEESE. The quick-ripened cheese made by the brick-cheese process from pressed curd obtained by the action of rennet on whole milk. It contains, in the water-free substance, not less than 50 per cent of milk fat.

6. STILTON CHEESE. The cheese made by the Stilton process from unpressed curd obtained by the action of rennet on whole milk, with or without added cream. During the ripening process a special blue-green mold develops, and the cheese thus acquires a marbled or mottled appearance in section.

7. GOUDA CHEESE. The cheese made by the Gouda process from heated and pressed curd obtained by the action of rennet on whole milk. The rind is colored with saffron. The finished cheese contains, in the water-free substance, not less than 45 per cent of milk fat.

8. NEUFCHATEL CHEESE. The cheese made by the Neufchatel process from unheated curd obtained by the combined action of lactic fermentation and rennet on whole milk. The curd, drained by gravity and light pressure, is kneaded or worked into a butterlike consistence and pressed into forms for immediate consumption or for ripening. The finished cheese contains, in the water-free substance, not less than 50 per cent of milk fat.

9. CREAM CHEESE. The unripened cheese made by the Neufchatel process from whole milk enriched with cream. It contains, in the water-free substance, not less than 65 per cent of milk fat.

10. ROQUEFORT CHEESE. The cheese made by the Roquefort process from unheated, unpressed curd obtained by the action of rennet on the whole milk of sheep, with or without the addition of a small proportion of the milk of goats.

[4] The term "whey cheese" has been applied to a variety of products, such as Ricotta, Zieger, Primost, Mysost, produced by various processes from the constituents of whey.

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The curd is inoculated with a special mold (*Penicillium roqueforti*) and ripens with the growth of the mold. The fully ripened cheese is friable and has a mottled or marbled appearance in section.

11. GORGONZOLA CHEESE. The cheese made by the Gorgonzola process from curd obtained by the action of rennet on whole milk. The cheese ripens in a cool, moist atmosphere with the development of a blue-green mold and thus acquires a mottled or marbled appearance in section.

Whole Milk or Skim Milk Cheese

12. EDAM CHEESE. The cheese made by the Edam process from heated and pressed curd obtained by the action of rennet on whole milk or on partly skimmed milk. It is commonly made in spherical form and coated with a suitable oil and a harmless red coloring matter.

13. SWISS CHEESE. The cheese made by the Emmenthaler process from heated and pressed curd obtained by the action of rennet on whole milk or on partly skimmed milk. It is ripened by special gas-producing bacteria, causing characteristic "eyes" or holes. The finished cheese contains, in the water-free substance, not less than 45 per cent of milk fat.

14. CAMEMBERT CHEESE. The cheese made by the Camembert process from unheated, unpressed curd obtained by the action of rennet on whole milk or on slightly skimmed milk. It is ripened by the growth of a special mold (*Penicillium camemberti*) on the outer surface. The finished cheese contains, in the water-free substance, not less than 45 per cent of milk fat.

15. BRIE CHEESE. The cheese made by the Brie process from unheated, unpressed curd obtained by the action of rennet on whole milk, on milk with added cream, or on slightly skimmed milk. It is ripened by the growth of a special mold on the outer surface.

16. PARMESAN CHEESE. The cheese made by the Parmesan process from heated and hard-pressed curd obtained by the action of rennet on partly skimmed milk. The cheese, during the long ripening process, is coated with a suitable oil.

17. COTTAGE CHEESE. The unripened cheese made from heated or unheated, separated curd obtained by the action of lactic fermentation or rennet, or a combination of the two, on skimmed milk, with or without the addition of buttermilk. The drained curd may be enriched with cream, and salted or otherwise seasoned.

Pasteurized Cheese

18. PASTEURIZED CHEESE, PASTEURIZED-BLENDED CHEESE. The pasteurized product made by comminuting and mixing, with the aid of heat and water, one or more lots of cheese into a homogeneous, plastic mass. The unqualified name "pasteurized cheese", "pasteurized-blended cheese", is understood to mean pasteurized Cheddar cheese, pasteurized-blended Cheddar cheese, and applies to a product which conforms to the standard for Cheddar cheese. Pasteurized cheese, pasteurized-blended cheese, bearing a varietal name is made from cheese of the variety indicated by the name and conforms to the limits for fat and moisture for cheese of that variety.

Process Cheese

19. PROCESS CHEESE. The modified cheese made by comminuting and mixing one or more lots of cheese into a homogeneous, plastic mass, with the aid of heat, with or without the addition of water, and with the incorporation of not more than 3 per cent of a suitable emulsifying agent. The name "process cheese" unqualified is understood to mean process Cheddar cheese, and applies

to a product which contains not more than 40 per cent of water and, in the water-free substance, not less than 50 per cent of milk fat. Process cheese qualified by a varietal name is made from cheese of the variety indicated by the name, and conforms to the limits for fat and moisture for cheese of that variety.

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VEGETABLE PRODUCTS

Grain Products

A. GRAIN AND FLOURS

1. GRAIN. The fully matured, air-dry seed of wheat, maize, rice, oats, rye, buckwheat, barley, sorghum, millet, or spelt.

2. RICE. The hulled, or hulled and polished, grain of *Oryza sativa* L.

a. Brown rice is hulled, unpolished grain.

b. Polished rice, "rice", is the hulled grain from which the bran or pericarp has been removed by scouring and rubbing.

3. MEAL. The product made by coarsely grinding grain.

4. CORN MEAL, MAIZE MEAL, INDIAN CORN MEAL. Meal made from maize grain. It contains not more than 14 per cent of moisture, not less than 1.12 per cent of nitrogen, and not more than 1.6 per cent of ash.

5. OATMEAL. Meal made from hulled oats. It contains not more than 12 per cent of moisture, not more than 1.5 per cent of crude fiber, not less than 2.24 per cent of nitrogen, and not more than 2.2 per cent of ash.

6. FLOUR, WHEAT FLOUR, WHITE FLOUR. The fine-ground product obtained in the commercial milling of wheat, consisting essentially of the starch and gluten of the endosperm. It contains not more than 15 per cent of moisture, not less than 1 per cent of nitrogen, not more than 1 per cent of ash, and not more than 0.5 per cent of fiber.

7. WHOLE-WHEAT FLOUR, ENTIRE-WHEAT FLOUR, GRAHAM FLOUR. The product made by grinding wheat, and containing, in their natural proportions, all of the constituents of the cleaned grain.

8. GLUTEN FLOUR. The product made from wheat flour by the removal of a large part of the starch. It contains not more than 10 per cent of moisture and, calculated on the water-free basis, not less than 7.1 per cent of nitrogen, not more than 56 per cent of nitrogen-free extract (using the protein factor 5.7), and not more than 44 per cent of starch (as determined by the diastase method).

9. GROUND GLUTEN. The product made from wheat flour by the almost complete removal of starch. It contains not more than 10 per cent of moisture and, calculated on the water-free basis, not less than 14.2 per cent of nitrogen, not more than 15 per cent of nitrogen-free extract (using the protein factor 5.7), and not more than 5.5 per cent of starch (as determined by the diastase method).

10. PURIFIED MIDDLINGS. The granular product obtained in the commercial process of milling wheat, and is that portion of the endosperm retained on 10 XX silk bolting cloth. It contains no more flour than is consistent with good commercial practice, nor more than 15 per cent of moisture.

11. SEMOLINA. The purified middlings of durum wheat.

12. FARINA. The purified middlings of hard wheat other than durum.

13. BUCKWHEAT FLOUR. Bolted buckwheat meal, containing not more than 12 per cent of moisture, not less than 1.28 per cent of nitrogen, and not more than 1.75 per cent of ash.

14. RYE FLOUR. The fine-ground product made by bolting rye meal. It contains not more than 13.5 per cent of moisture, not less than 1.36 per cent of nitrogen, and not more than 1.25 per cent of ash.

B. BREADS

1. BREAD. The product made by baking a dough consisting of a leavened or unleavened mixture of ground grain and/or other edible farinaceous substance, with water, and with or without the addition of other edible substances.

2. WHITE BREAD. The product, in the form of loaves or smaller units, obtained by baking a leavened and kneaded mixture of flour, water, salt, and yeast, with or without edible fat or oil, milk or a milk product, sugar and/or other fermentable carbohydrate substance. It may also contain diastatic and/or proteolytic ferments and such minute amounts of unobjectionable salts as serve solely as yeast nutrients. The flour ingredient may include not more than

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8 per cent of other edible farinaceous substance. White bread contains, 1 hour or more after baking, not more than 38 per cent of moisture. The name "bread" unqualified is commonly understood to mean white bread.

3. WHOLE-WHEAT BREAD, ENTIRE-WHEAT BREAD, GRAHAM BREAD. The product, in the form of loaves or smaller units, obtained by baking a leavened and kneaded mixture of whole-wheat flour, water, salt, and yeast, with or without edible fat or oil, milk or a milk product, sugar and/or other fermentable carbohydrate substance. It may also contain diastatic and/or proteolytic ferments and such minute amounts of unobjectionable salts as serve solely as yeast nutrients. It contains, 1 hour or more after baking, not more than 38 per cent of moisture.

4. MILK BREAD. The product, in the form of loaves or smaller units, obtained by baking a leavened and kneaded mixture of flour, salt, yeast, and milk or its equivalent (milk solids and water in the proportions normal to milk); with or without edible fat or oil, sugar and/or other fermentable carbohydrate substance. It may also contain diastatic and/or proteolytic ferments and such minute amounts of unobjectionable salts as serve solely as yeast nutrients. The flour ingredient may include not more than 3 per cent of other edible farinaceous substance. Milk bread contains, 1 hour or more after baking, not more than 38 per cent of moisture.

5. RAISIN BREAD. The product, in the form of loaves or smaller units, obtained by baking a leavened and kneaded mixture of flour, water, salt, yeast, and raisins, with or without edible fat or oil, milk or a milk product, sugar and/or other fermentable carbohydrate substance. It may contain diastatic and/or proteolytic ferments and such minute amounts of unobjectionable salts as serve solely as yeast nutrients. The flour ingredient may include not more than 3 per cent of other edible farinaceous substance. The finished product contains not less than 3 ounces of raisins to the pound.

6. BOSTON BROWN BREAD. The product, commonly in the form of cylindrical loaves, obtained by steaming or baking a leavened mixture of rye flour or meal, corn meal, a wheat flour, molasses, salt, water, and/or a milk product, with or without raisins. Leavening is commonly effected through the use of baking powder or sodium bicarbonate and sour milk.

C. MACARONI AND NOODLES

1. MACARONI. The shaped and dried doughs prepared by adding water to one or more of the following: Semolina, farina, wheat flour. It may contain added salt. In the finished product the moisture content does not exceed 13 per cent. Various shapes of macaroni are known under distinguishing names, such as spaghetti, vermicelli.

a. Semolina macaroni is macaroni in the preparation of which semolina is the sole farinaceous ingredient.

b. Farina macaroni is macaroni in the preparation of which farina is the sole farinaceous ingredient.

2. NOODLES, EGG NOODLES. The shaped and dried doughs prepared from wheat flour and eggs, with or without water and with or without salt. The egg ingredient may be whole egg and/or egg yolk. In the finished product the moisture content does not exceed 13 per cent and the egg-solids content upon the moisture-free basis is not less than 5.5 per cent. Noodles are commonly ribbon-shaped.

3. PLAIN NOODLES. The shaped and dried doughs prepared from wheat flour and water, with or without salt. In the finished product the moisture content does not exceed 13 per cent. Plain noodles are commonly ribbon-shaped.

Fruits and Vegetables

A. Fruit and Fruit Products

Citrus Fruits

1. GRAPEFRUIT, POMELO. The mature fruit of *Citrus grandis* Osbeck. The juice of the mature fruit contains not less than 7 parts of "soluble solids" (Brix reading expressed as sucrose) to each part of acid calculated as citric acid without water of crystallization.

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2. ORANGE (common, sweet, or round). The mature fruit of *Citrus sinensis* Osbeck. The juice of the mature fruit contains not less than 8 parts of "soluble solids" (Brix reading expressed as sucrose) to each part of acid calculated as citric acid without water of crystallization.

Dried Fruits

3. EVAPORATED APPLES. Peeled, cored, and sliced apples from which the greater portion of the moisture has been evaporated. The finished product contains not more than 24 per cent of moisture.

4. DRIED APRICOTS. Halved and pitted ripe apricots from which the greater portion of the moisture has been evaporated. Before packing, the dried fruit is commonly processed by washing. The finished product contains not more than 26 per cent of moisture.

5. DRIED PEACHES. Halved and pitted ripe peaches from which the greater portion of the moisture has been evaporated. Before packing, the dried fruit is commonly processed by washing. The finished product contains not more than 26 per cent of moisture.

6. DRIED PRUNES. Whole ripe prune plums from which the greater portion of the moisture has been evaporated. Before packing, the dried fruit is commonly processed by treatment with boiling water or steam. The finished product contains, in the fleshly portion, not more than 25 per cent of moisture.

Cold-Pack Fruit

7. COLD-PACK FRUIT. The product obtained by packing, in a suitable container, properly prepared fresh fruit, with or without the addition of sugar and/or dextrose, and maintaining it at a temperature sufficiently low to insure its preservation.

Preserves, Jams, Jellies

8. PRESERVE, FRUIT PRESERVE, JAM, FRUIT JAM. The product made by cooking to a suitable consistence properly prepared fresh fruit, cold-pack

fruit, canned fruit, or a mixture of two or all of these, with sugar or with sugar and dextrose, with or without water. In its preparation not less than 45 pounds of fruit are used to each 55 pounds of sugar or of sugar and dextrose. A product in which the fruit is whole or in relatively large pieces is customarily designated a "preserve" rather than a "jam."

9. JELLY, FRUIT JELLY. The semisolid, gelatinous product made by concentrating to a suitable consistence the strained juice or the strained water extract from fresh fruit, from cold-pack fruit, from canned fruit, or from a mixture of two or of all of these, with sugar or with sugar and dextrose.

10. GLUCOSE FRUIT PRESERVE, CORN SIRUP FRUIT PRESERVE, GLUCOSE FRUIT JAM, CORN SIRUP FRUIT JAM. The product made by cooking to a suitable consistence properly prepared fresh fruit, cold-pack fruit, canned fruit, or a mixture of two or all of these, with glucose or corn sirup. In its preparation not less than 45 pounds of fruit are used to each 55 pounds of glucose or corn sirup.

11. GLUCOSE FRUIT JELLY, CORN SIRUP FRUIT JELLY. The semisolid, gelatinous product made by concentrating to a suitable consistence the strained juice or the strained water extract from fresh fruit, from cold-pack fruit, from canned fruit, or from a mixture of two or of all of these, with glucose or corn sirup.

12. CITRUS FRUIT MARMALADE. The jellylike product made from the properly prepared peel and juice, with or without the pulp, of citrus fruit, with sugar or with sugar and dextrose, by cooking with water. It contains, embedded in the mass, pieces of the fruit peel.

13. APPLE BUTTER. The semisolid product obtained by cooking to a suitable consistence the strained edible portion of apples with sugar and/or dextrose, with or without one or more of the following: Apple juice, boiled cider, spice, salt. In its preparation not less than 5 parts by weight of the strained apples are used to each 2 parts by weight of sugar and/or dextrose. The product has a characteristic apple flavor and is commonly spiced.

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B. FRUIT JUICES

1. FRUIT JUICE. The unfermented liquid obtained from the first pressing of sound, ripe, fresh fruit or its pulp. It conforms in name to the fruit from which it is obtained.

2. GRAPE JUICE. The unfermented juice of sound, ripe grapes. It is obtained by a single pressing of the fruit, with or without the aid of heat, and with or without the removal of insoluble matter.

3. ORANGE JUICE. The unfermented juice obtained from sound, ripe, sweet oranges. It may contain a portion of the pulp.

C. FRUIT KERNEL PASTES

1. KERNEL PASTES. The plastic products obtained by cooking with water, sugar, and/or dextrose, the blanched and ground kernels of one or more of the following: Apricots, peaches, plums (prunes). They are free from hydrocyanic acid and contain not more than 14 per cent of water nor more than 40 per cent of total sugars expressed as invert sugar. A kernel paste conforms in name to the kind or kinds of kernels employed in its production.

2. ALMOND PASTE. The kernel paste obtained by cooking blanched and ground sweet almonds with blanched and ground bitter almonds, water, sugar, and/or dextrose. It contains not more than 14 per cent of water nor more than 40 per cent of total sugars expressed as invert sugar.

D. TOMATO PRODUCTS

1. TOMATO PUREE,[5] TOMATO PULP. The product resulting from the concentration of the screened or strained fleshy and liquid portions of ripe tomatoes, except those portions from skin and core trimmings; with or without the addition of salt. The product contains not less than 8.37 per cent of tomato solids.

2. TOMATO PASTE SALSA DI POMODORO, "SALSA." The product resulting from the concentration of the screened or strained fleshy and liquid portions of ripe tomatoes, except those portions from skin and core trimmings; with or without the addition of salt, and with or without the addition of basil. The finished product contains not less than *22* per cent of tomato solids.

3. HEAVY TOMATO PASTE, "CONCENTRATO." Tomato paste containing not less than 33 per cent of tomato solids.

4. TOMATO JUICE. The unconcentrated, pasteurized product, consisting of the liquid, with a substantial portion of the pulp, expressed from ripe tomatoes, with or without the application of heat, and with or without the addition of salt.

5. TOMATO CATCHUP. The concentrated product made from the pulp and juice of ripe tomatoes (exclusive of skins, seeds, and cores), a vinegar, salt, spice, and other seasoning, sugar and/or dextrose.

E. PICKLES

1. PICKLES. Immature cucumbers properly prepared, without taking up any metallic compounds other than salt, and preserved in any kind of vinegar, with or without spices. Pickled onions, pickled beets, pickled beans, and other pickled vegetables are vegetables prepared as described above, and conform in name to the vegetables used.

2. SALT PICKLES. Immature cucumbers preserved in a solution of common salt, with or without spices.

3. SWEET PICKLES. Pickled cucumbers or other vegetables sweetened with sugar and/or dextrose.

F. SAUERKRAUT

SAUERKRAUT. The product, of characteristic acid flavor, obtained by the full fermentation, chiefly lactic, of properly prepared and shredded cabbage in the presence of not less than *2* per cent nor more than 3 per cent of salt. It contains, upon completion of the fermentation, not less than 1.5 per cent of acid, expressed as lactic acid. Sauerkraut which has been rebrined in the process of canning or repacking, contains not less than 1 per cent of acid, expressed as lactic acid.

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SUGARS AND RELATED SUBSTANCES

A. SUGAR AND SUGAR PRODUCTS

1. SUGAR. Sucrose (saccharose) obtained chiefly from sugarcane and sugar beets. Granulated, loaf, cut, milled, and powdered sugars are different forms of sugar, containing at least 99.5 per cent of sucrose.

2. MOLASSES. The product left after separating the sugar from massecuite, melada, mush sugar, or concrete. It contains not more than 25 per cent of water and not more than 5 per cent of ash.

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[5] "Tomato puree" should not be confused with "puree from trimmings", a term used to denote a product, commonly unconcentrated, sometimes added in the canning of tomatoes.

3. REFINERS SIRUP. The residual liquid product obtained in the process of refining raw cane sugars. It contains not more than 25 per cent of water and not more than 8 per cent of ash.

4. CANE SIRUP. Sirup made by the evaporation of the juice of the sugarcane or by the solution of sugarcane concrete. It contains not more than 30 per cent of water and not more than 2.5 per cent of ash.

5. SUGAR SIRUP. The sirup made by dissolving sugar in water. It contains not more than 35 per cent of water.

6. MAPLE SUGAR. The solid product resulting from the evaporation of maple sap or maple sirup.

7. MAPLE SYRUP. Sirup made by the evaporation of maple sap, or by the solution of maple sugar. It contains not more than 35 per cent of water. The finished product weighs not less than 11 pounds to the gallon (231 cubic inches).

8. SORGHUM SIRUP. The sirup obtained by the clarification and concentration of the juice of the sugar sorghum. It contains not more than 30 per cent of water, nor more than 6.25 per cent of ash calculated on a dry basis.

B. DEXTROSE AND RELATED PRODUCTS

1. DEXTROSE. The product chiefly made by the hydrolysis of starch or a starch-containing substance, followed by processes of refining and crystallization.[6]

a. Anhydrous dextrose contains not less than 99.5 per cent of dextrose and not more than 0.5 per cent of moisture.

b. Hydrated dextrose contains not less than 90 per cent of dextrose and not more than 10 per cent of moisture, including water of crystallization.

2. GLUCOSE, MIXING GLUCOSE, CONFECTIONER'S GLUCOSE. A thick, sirupy, colorless product made by incompletely hydrolyzing starch, or a starch-containing substance, and decolorizing and evaporating the product. It contains on a basis of 41° Baumé not more than 1 per cent of ash, consisting chiefly of chlorides and sulphates.

C. HONEY

1. HONEY. The nectar and saccharine exudations of plants gathered, modified, and stored in the comb by honeybees (*Apis mellifica* and *A. dorsata.*). Honey is levorotatory and contains not more than 25 per cent of water, not more than 0.25 per cent of ash, and not more than 8 per cent of sucrose.

2. COMB HONEY. Honey contained in the cells of comb.

3. EXTRACTED HONEY. Honey which has been separated from the uncrushed comb by centrifugal force or gravity.

4. STRAINED HONEY. Honey removed from the crushed comb by straining or other means.

CONDIMENTS

A. SPICES[7]

1. SPICES. Aromatic vegetable substances used for the seasoning of food. They are true to name, and from them no portion of any volatile oil or other flavoring principle has been removed.

2. ALLSPICE, PIMENTO. The dried, nearly ripe fruit of *Pimenta officinalis* Lindl. It contains not less than 8 per cent of quercitannic acid (calculated

[6] When derived from cornstarch, dextrose is known commercially as refined corn sugar.

[7] The term "dried" as used in this schedule refers to the air-dried product. The term "starch" as used in this schedule refers to starch as determined by the official diastase method.

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from the total oxygen absorbed by the aqueous extract), not more than 25 per cent of crude fiber, not more than 6 per cent of total ash, nor more than 0.4 per cent of ash insoluble in hydrochloric acid.

3. ANISE, ANISEED. The dried fruit of *Pimpinella anisum* L. It contains not more than 9 per cent of total ash, nor more than 1.5 per cent of ash insoluble in hydrochloric acid.

4. BAY LEAVES. The dried leaves of *Laurus nobilis* L.

5. CAPERS. The flower buds of *Capparis spinosa* L.

6. CARAWAY, CARAWAY SEED. The dried fruit of *Carum carvi* L. It contains not more than 8 per cent of total ash, nor more than 1.5 per cent of ash insoluble in hydrochloric acid.

7. CARDAMOM. The dried, nearly ripe fruit of *Elettaria cardamomum* Maton.

8. CARDAMOM SEED. The dried seed of cardamom. It contains not more than 8 per cent of total ash, nor more than 3 per cent of ash insoluble in hydrochloric acid.

9. RED PEPPER. The red, dried, ripe fruit of any species of *Capsicum*. It contains not more than 8 per cent of total ash, nor more than 1 per cent of ash insoluble in hydrochloric acid.

10. CAYENNE PEPPER, CAYENNE. The dried, ripe fruit of *Capsicum frutescens*, L., *C. baccatum* L., or some other small-fruited species of *Capsicum*. It contains not less than 15 per cent of nonvolatile ether extract, not more than 1.5 per cent of starch, not more than 28 per cent of crude fiber, not more than 8 per cent of total ash, nor more than 1.25 per cent of ash insoluble in hydrochloric acid.

11. PAPRIKA. The dried, ripe fruit of *Capsicum annuum* L. It contains not more than 8.5 per cent of total ash, nor more than 1 per cent of ash insoluble in hydrochloric acid. The iodine number of its extracted oil is not less than 125, nor more than 136.

12. HUNGARIAN PAPRIKA. Paprika having the pungency and flavor characteristic of that grown in Hungary.

a. Rosenpaprika, rosapaprika, rose paprika, is Hungarian paprika prepared by grinding specially selected pods of paprika, from which the placentae, stalks, and stems have been removed. It contains no more seeds than the normal pods, not more than 18 per cent of nonvolatile ether extract, not more than 23 per cent of crude fiber, not more than 6 per cent of total ash, nor more than 0.4 per cent of ash insoluble in hydrochloric acid.

b. Koenigspaprika, king's paprika, is Hungarian paprika prepared by grinding whole pods of paprika without selection, and includes the seeds and stems naturally occurring with the pods. It contains not more than 18 per cent of nonvolatile ether extract, not more than 23 per cent of crude fiber, not more than 6.5 per cent of total ash, nor more than 0.5 per cent of ash insoluble in hydrochloric acid.

13. PIMENTON, PIMIENTO, SPANISH PAPRIKA. Paprika having the characteristics of that grown in Spain. It contains not more than 18 per cent of nonvolatile ether extract, not more than 21 per cent of crude fiber, not more than 8.5 per cent of total ash, nor more than 1 per cent of ash insoluble in hydrochloric acid.

14. CELERY SEED. The dried fruit of *Celeri graveolens* (L.) Britton (*Apium graveolens* L.). It contains not more than 10 per cent of total ash, nor more than 2 per cent of ash insoluble in hydrochloric acid.

15. CINNAMON. The dried bark of cultivated varieties of *Cinnamomum zeylanicum* Nees or of *C. cassia* (L.) Blume, from which the outer layers may or may not have been removed.

16. CEYLON CINNAMON. The dried inner bark of cultivated varieties of *Cinnamomum zeylanicum* Nees.

17. SAIGON CINNAMON, CASSIA. The dried bark of cultivated varieties of *Cinnamomum cassia* (L.) Blume.

18. GROUND CINNAMON, GROUND CASSIA. The powder made from cinnamon. It contains not more than 5 per cent of total ash, nor more than 2 per cent of ash insoluble in hydrochloric acid.

19. CLOVES. The dried flower buds of *Caryophyllus aromaticus* L. They contain not more than 5 per cent of clove stems, not less than 15 per cent of volatile ether extract, not less than 12 per cent of quercitannic acid (calculated from the total oxygen absorbed by the aqueous extract), not more than 10 per cent of crude fiber, not more than 7 per cent of total ash, nor more than 0.5 per cent of ash insoluble in hydrochloric acid.

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20. CORIANDER SEED. The dried fruit of *Coriandrum sativum* L. It contains not more than 7 per cent of total ash, nor more than 1.5 per cent of ash insoluble in hydrochloric acid.

21. CUMIN SEED. The dried fruit of *Cuminum cyminum* L. It contains not more than 9.5 per cent of total ash, not more than 1.5 per cent of ash insoluble in hydrochloric acid, nor more than 5 per cent of harmless foreign matter.

22. CURCUMA TURMERIC. The dried rhizome or bulbous root of *Curcuma longa* L.

23. DILL SEED. The dried fruit of *Anethum graveolens* L. It contains not more than 10 per cent of total ash, nor more than 3 per cent of ash insoluble in hydrochloric acid.

24. FENNEL SEED. The dried fruit of cultivated varieties of *Foeniculum vulgare* Hill. It contains not more than 9 per cent of total ash nor more than 2 per cent of ash insoluble in hydrochloric acid.

25. GINGER. The washed and dried, or decorticated and dried, rhizome of *Zingiber officinale* Roscoe. It contains not less than 42 per cent of starch, not more than 8 per cent of crude fiber, not more than 1 per cent of lime (CaO), not less than 12 per cent of cold-water extract, not more than 7 per cent of total ash, not more than 2 per cent of ash insoluble in hydrochloric acid, nor less than 2 per cent of ash soluble in cold water.

26. JAMAICA GINGER. Ginger grown in Jamaica. It contains not less than 15 per cent of cold-water extract, and conforms in other respects to the standards for ginger.

27. LIMED GINGER, BLEACHED GINGER. Whole ginger coated with carbonate of calcium. It contains not more than 4 per cent of carbonate of calcium nor more than 10 per cent of total ash, and conforms in other respects to the standards for ginger.

28. HORSERADISH. The root of *Radicula armoracia* (L.) Robinson.

29. PREPARED HORSERADISH. Comminuted horseradish, with or without a vinegar.

30. MACE. The dried arillus of *Myristica fragrans* Houtt. It contains not less than 20 per cent nor more than 30 per cent of nonvolatile ether extract, not more than 10 per cent of crude fiber, not more than 3 percent of total ash, nor more than 0.5 per cent of ash insoluble in hydrochloric acid.

31. MACASSAR MACE, PAPUA MACE. The dried arillus of *Myristica argentea* Warb.

32. MARJORAM, LEAF MARJORAM. The dried leaves, with or without a small proportion of the flowering tops, of *Majorana hortensis* Moench. It contains not more than 16 per cent of total ash, not more than 4.5 per cent of ash insoluble in hydrochloric acid, nor more than 10 per cent of stems and harmless foreign material.

33. MUSTARD SEED. The seed of *Sinapis alba* L. (white mustard), *Brassica nigra* (L.) Koch (black mustard), *B. juncea* (L.) Cosson, or varieties or closely related species of the types of *B. nigra* and *B. juncea*.

Sinapis alba (white mustard) contains no appreciable amount of volatile oil. It contains not more than 5 per cent of total ash nor more than 1.5 per cent of ash insoluble in hydrochloric acid.

Brassica nigra (black mustard) and *B. juncea* yield 0.6 per cent of volatile mustard oil (calculated as allylisothiocyanate). The varieties and species closely related to the types of *B. nigra* and *B. juncea* yield not less than 0.6 per cent of volatile mustard oil, similar in character and composition to the volatile oils yielded by *B. nigra* and *B. juncea*. These mustard seeds contain not more than 5 per cent of total ash, nor more than 1.5 per cent of ash insoluble in hydrochloric acid.

34. GROUND MUSTARD SEED, MUSTARD MEAL. Unbolted, ground mustard seed, conforming to the standards for mustard seed.

35. MUSTARD CAKE. Ground mustard seed, mustard meal, from which a portion of fixed oil has been removed.

36. MUSTARD FLOUR, GROUND MUSTARD, "MUSTARD". The powder made from mustard seed with the hulls largely removed and with or without the removal of a portion of the fixed oil. It contains not more than 1.5 per cent of starch, nor more than 6 per cent of total ash.

37. PREPARED MUSTARD. A paste composed of a mixture of ground mustard seed and/or mustard flour and/or mustard cake, with salt, a vinegar, and with or without sugar and/or dextrose, spices, or other condiments. In the fat-, salt-, and sugar-free solids it contains not more than 24 per cent of

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carbohydrates, not more than 12 per cent of crude fiber, nor less than 5.6 per cent of nitrogen, the carbohydrates being calculated as starch.

38. NUTMEG. The dried seed of *Myristica fragrans* Houtt. deprived of its testa, with or without a thin coating of lime (CaO). It contains not less than 25 per cent of nonvolatile ether extract, not more than 10 per cent of crude fiber, not more than 5 per cent of total ash, nor more than 0.5 per cent of ash insoluble in hydrochloric acid.

39. MACASSAR NUTMEG, PAPUA NUTMEG, MALE NUTMEG, LONG NUTMEG. The dried seed of *Myristica argentea* Warb. deprived of its testa.

40. PARADISE SEED, GRAINS OF PARADISE, GUINEA GRAINS, MELEGUETA PEPPER. The seed of *Amomum melegueta* Roscoe.

41. PARSLEY LEAVES. The leaves of *Petroslinum hortense* Hoffm. (*P. sativum* Hoffm.).

42. BLACK PEPPER. The dried immature berry of *Piper nigrum* L. It contains not less than 6.75 per cent of nonvolatile ether extract, not less than 30 per cent of starch, not more than 7 per cent of total ash, nor more than 1.5 per cent of ash insoluble in hydrochloric acid.

43. GROUND BLACK PEPPER. The product made by grinding the entire berry of *Piper nigrum* L. It contains the several parts of the berry in their normal proportions.

44. LONG PEPPER. The dried fruit of *Piper longum* L.

45. WHITE PEPPER. The dried mature berry of *Piper nigrum* L. from which the outer coating (or the outer and inner coatings) have been removed. It contains not less than 7 per cent of nonvolatile ether extract, not less than 52 per cent of starch, not more than 5 per cent of crude fiber, not more than 3.5 per cent of total ash, nor more than 0.3 per cent of ash insoluble in hydrochloric acid.

46. SAFFRON. The dried stigma of *Crocus sativus* L. It contains not more than 10 per cent of yellow styles and other foreign matter, not more than 14 per cent of volatile matter when dried at 100° C., not more than 7.5 per cent of total ash, nor more than 1 per cent of ash insoluble in hydrochloric acid.

47. SAGE. The dried leaf of *Salvia officinalis* L. It contains not more than 12 per cent of stems (excluding petioles) and other foreign material.

48. SAVORY, SUMMER SAVORY. The dried leaves and flowering tops of *Satureja hortense* L.

49. STAR ANISEED. The dried fruit of *Illicium verum* Hook. It contains not more than 5 per cent of total ash.

50. TARRAGON. The dried leaves and flowering tops of *Artemisia dracunculus* L.

51. THYME. The dried leaves and flowering tops of *Thymus vulgaris* L. It contains not more than 14 per cent of total ash, nor more than 4 per cent of ash insoluble in hydrochloric acid.

B. FLAVORING EXTRACTS AND ESSENTIAL OILS

1. FLAVORING EXTRACTS.[a] A solution in ethyl alcohol of proper strength of the sapid and odorous principles derived from an aromatic plant, or parts of the plant, with or without its coloring matter, conforming in name to the plant used in its preparation.

2. ALMOND EXTRACT. The flavoring extract prepared from oil of bitter almonds, free from hydrocyanic acid. It contains not less than 1 per cent by volume of oil of bitter almonds.

2a. OIL OF BITTER ALMONDS, COMMERCIAL. The volatile oil obtained from the seed of the bitter almond (*Amygdalus communis* L.), the apricot (*Prunus armeniaca* L.), or the peach (*Amygdalus persica* L.).

3. ANISE EXTRACT. The flavoring extract prepared from oil of anise. It contains not less than 3 per cent by volume of oil of anise.

3a. OIL OF ANISE. The volatile oil obtained from aniseed.

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[a] The flavoring extracts herein described are intended solely for food purposes and are not to be confounded with similar preparations described in the Pharmacopoeia for medicinal purposes.

4. CELERY SEED EXTRACT. The flavoring extract prepared from celery seed or the oil of celery seed, or both. It contains not less than 0.3 per cent by volume of oil of celery seed.

4a. OIL OF CELERY SEED. The volatile oil obtained from celery seed.

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5. CINNAMON EXTRACT, CASSIA EXTRACT, CASSIA CINNAMON EXTRACT. The flavoring product prepared from oil of cinnamon. It contains not less than 2 per cent by volume of oil of cinnamon.

5a. OIL OF CINNAMON, OIL OF CASSIA, OIL OF CASSIA CINNAMON. The lead-free volatile oil obtained from the leaves or bark of *Cinnamomum cassia* (L.) Blume. It contains not less than 80 per cent by volume of cinnamic aldehyde.

6. CEYLON CINNAMON EXTRACT. The flavoring extract prepared from oil of Ceylon cinnamon. It contains not less than 2 per cent by volume of oil of Ceylon cinnamon.

6a. OIL OF CEYLON CINNAMON. The lead-free volatile oil obtained from the bark of the Ceylon cinnamon (*Cinnamomum zeylanicum* Nees). It contains not less than 65 per cent by weight of cinnamic aldehyde and not more than 10 per cent by weight of eugenol.

7. CLOVE EXTRACT. The flavoring extract prepared from oil of cloves. It contains not less than 2 per cent by volume of oil of cloves.

7a. OIL OF CLOVES. The lead-free volatile oil obtained from cloves.

8. GINGER EXTRACT. The flavoring extract prepared from ginger. It contains in each 100 cubic centimeters the alcohol-soluble matters from not less than 20 grams of ginger.

9. LEMON EXTRACT. The flavoring extract prepared from oil of lemon, or from lemon peel, or both. It contains not less than 5 per cent by volume of oil of lemon.

9a. OIL OF LEMON. The volatile oil expressed, without the aid of heat, from the fresh peel of the lemon (*Citrus limonia* Osbeck), with or without previous separation of the pulp and peel.

10. TERPENELESS EXTRACT OF LEMON. The flavoring extract prepared by shaking oil of lemon with dilute alcohol, or by dissolving terpeneless oil of lemon in dilute alcohol. It contains not less than 0.2 per cent by weight of citral derived from oil of lemon.

10a. TERPENELESS OIL OF LEMON. Oil of lemon from which all or nearly all of the terpenes have been removed.

11. NUTMEG EXTRACT. The flavoring extract prepared from oil of nutmeg. It contains not less than 2 per cent by volume of oil of nutmeg.

11a. OIL OF NUTMEG. The volatile oil obtained from nutmegs.

12. ORANGE EXTRACT. The flavoring extract prepared from oil of orange, or from orange peel, or both. It contains not less than 5 per cent by volume of oil of orange.

12a. OIL OF ORANGE. The volatile oil obtained, by expression or alcoholic solution, from the fresh peel of the orange (*Citrus aurantium* L.). It has an optical rotation (25° C.) of not less than +95° in a 100-millimeter tube.

13. TERPENELESS EXTRACT OF ORANGE. The flavoring extract prepared by shaking oil of orange with dilute alcohol, or by dissolving terpeneless oil of orange in dilute alcohol. It corresponds in flavoring strength to orange extract.

13a. TERPENELESS OIL OF ORANGE. Oil of orange from which all or nearly all of the terpenes have been removed.

14. PEPPERMINT EXTRACT. The flavoring extract prepared from oil of peppermint, or from peppermint, or both. It contains not less than 3 per cent by volume of oil of peppermint.

14a. PEPPERMINT. The leaves and flowering tops of *Mentha piperita* L.

14b. OIL OF PEPPERMINT. The volatile oil obtained from peppermint. It contains not less than 50 per cent by weight of menthol.

15. ROSE EXTRACT. The flavoring extract prepared from attar of roses, with or without red rose petals. It contains not less than 0.4 per cent by volume of attar of roses.

15a. ATTAR OF ROSES. The volatile oil obtained from the petals of *Rosa Damascena* Mill., *R. centifolia* L., or *R. moschata* Herrm.

16. SAVORY EXTRACT. The flavoring extract prepared from oil of savory, or from savory, or both. It contains not less than 0.35 per cent by volume of oil of savory.

16a. OIL OF SAVORY. The volatile oil obtained from savory.

17. SPEARMINT EXTRACT. The flavoring extract prepared from oil of spearmint, or from spearmint, or both. It contains not less than 3 per cent by volume of oil of spearmint.

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17a. SPEARMINT. The leaves and flowering tops of *Mentha spicata* L.

17b. OIL OF SPEARMINT. The volatile oil obtained from spearmint.

18. STAR ANISE EXTRACT. The flavoring extract prepared from oil of star anise. It contains not less than 3 percent by volume of oil of star anise.

18a. OIL OF STAR ANISE. The volatile oil distilled from the fruit of the star anise (*Illicium verum* Hook.).

19. SWEET BASIL EXTRACT. The flavoring extract prepared from oil of sweet basil, or from sweet basil, or both. It contains not less than 0.1 per cent by volume of oil of sweet basil.

19a. SWEET BASIL, BASIL. The leaves and tops of *Ocinum basilicum* L.

19b. OIL OF SWEET BASIL. The volatile oil obtained from basil.

20. SWEET MARJORAM EXTRACT, MARJORAM EXTRACT. The flavoring extract prepared from the oil of marjoram, or from marjoram, or both. It contains not less than 1 per cent by volume of oil of marjoram.

20a. OIL OF MARJORAM. The volatile oil obtained from marjoram.

21. THYME EXTRACT. The flavoring extract prepared from oil of thyme, or from thyme, or both. It contains not less than 0.2 per cent by volume of oil of thyme.

21a. OIL OF THYME. The volatile oil obtained from thyme.

22. TONKA EXTRACT. The flavoring extract prepared from tonka bean, with or without one or more of the following: Sugar, dextrose, glycerin. It contains not less than 0.1 per cent by weight of coumarin extracted from the tonka bean, together with a corresponding proportion of the other soluble matters thereof.

22a. TONKA BEAN. The seed of *Coumarouna odorata* Aublet (*Dipteryx odorata* (Aubl.) Willd.).

23. VANILLA EXTRACT. The flavoring extract prepared from vanilla bean, with or without one or more of the following: Sugar, dextrose, glycerin. It contains in 100 cubic centimeters the soluble matters from not less than 10 grams of the vanilla bean.

23a. VANILLA BEAN. The dried cured fruit of *Vanilla fragrans* (Salisb.) Ames (*V. planifolia* Andr.).

24. WINTERGREEN EXTRACT. The flavoring extract prepared from oil of wintergreen. It contains not less than 3 per cent by volume of oil of wintergreen.

24a. OIL OF WINTERGREEN. The volatile oil distilled from the leaves of *Gaultheria procumbens* L.

c. MAYONNAISE DRESSING.

MAYONNAISE, MAYONNAISE DRESSING, MAYONNAISE SALAD DRESSING. The semisolid emulsion of edible vegetable oil, egg yolk, or whole egg, a vinegar, and/or lemon juice, with one or more of the following: Salt, other seasoning commonly used in its preparation, sugar, and/or dextrose. The finished product contains not less than 50 per cent of edible vegetable oil.

EDIBLE VEGETABLE OILS AND FATS

1. EDIBLE FATS and EDIBLE OILS. Such glycerids of the fatty acids as are recognized to be wholesome foods. They are dry, and sweet in flavor and odor.

2. CACAO BUTTER, COCOA BUTTER. The edible fat obtained from sound cacao beans (seeds of *Theobroma cacao* L. or other closely related species), either before or after roasting.

3. COCONUT OIL, COPRA OIL. The edible oil obtained from the kernels of the coconut (*Cocos nucifera* L. or *C. butyracea* L.).

a. Cochin oil is coconut oil prepared in Cochine (Malabar).

b. Ceylon oil is coconut oil prepared in Ceylon.

4. CORN OIL, MAIZE OIL. The edible oil obtained from the germ of Indian corn, maize (*Zea mays* L.).

5. COTTONSEED OIL. The edible oil obtained from the seed of the cotton plant (*Gossypium herbaceum* L.), or from the seed of other species of *Gossypium*.

6. OLIVE OIL, SWEET OIL. The edible oil obtained from the sound, mature fruit of the olive tree (*Olea europaea* L.).

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7. PALM KERNEL OIL. The edible oil obtained from the kernels of the fruit of the palm tree (*Elaeis guineensis* Jacq., or *E. melanococca* Gaert.).

8. PEANUT OIL, ARACHIS OIL, EARTHNUT OIL. The edible oil obtained from the peanut (*Arachis hypogaea* L.).

9. POPPY-SEED OIL. The edible oil obtained from the seeds of the poppy (*Papaver somniferum* L.).

10. RAPESEED OIL, RAPE OIL, COLZA OIL. The edible oil obtained from the seed of the rape plant (*Brassica napus* L.), or from the seed of closely related *Brassica* species which yield oils similar in composition and character to the oil obtained from the seed of *B. napus* L.

11. SOYBEAN OIL, SOY OIL, SOJA OIL. The edible oil obtained from the seed of the soybean plant (*Soja max.* (L.) Piper; *Glycine soja* Sieb. and Zucc.; *Soja hispida* Moench).

12. SESAME OIL, GINGILLI OIL, TEEL OIL, BENNE OIL. The edible oil obtained from the seed of the sesame plant (*Sesamum orientale* L.; *S. indicum* L.; *S. radiatum* Schum. and Thonn.).

13. SUNFLOWER OIL. The edible oil obtained from the seed of the sunflower (*Helianthus annuus* L.).

Tea, Coffee, and Cacao Products

A. TEA

TEA. The tender leaves, leaf buds, and tender internodes of different varieties of *Thea sinensis* L., prepared and cured by recognized methods of manufacture. It conforms in variety and place of production to the name it bears; contains not less than 4 per cent nor more than 7 per cent of ash; and meets the provisions of the act of Congress approved March 2, 1897, as amended, regulating the importation and inspection of tea.

B. COFFEE

COFFEE. The seed of cultivated varieties of *Coffea arabica, C. liberica,* and *C. robusta.*

a. Green coffee, raw coffee, unroasted coffee, is coffee freed from all but a small portion of its spermoderm, and conforms in variety and in place of production to the name it bears.

b. Roasted coffee, "coffee", is properly cleaned green coffee which by the action of heat (roasting) has become brown and has developed its characteristic aroma.

C. CACAO PRODUCTS

1. CACAO BEANS, COCOA BEANS. The seeds of trees belonging to the genus *Theobroma,* especially those of *T. cacao* L. and closely related species.

2. CACAO NIBS, COCOA NIBS, "CRACKED COCOA." Roasted or dried cacao beans, broken and freed from germ and from shell or husk.

3. CACAO BUTTER, COCOA BUTTER. (See Edible Vegetable Oils and Fats.)

4. CHOCOLATE, PLAIN CHOCOLATE, BITTER CHOCOLATE, CHOCOLATE LIQUOR, CHOCOLATE PASTE, BITTER CHOCOLATE COATING. The solid or plastic mass obtained by grinding cacao nibs. It contains not less than 50 per cent of cacao fat and, on the moisture- and fat-free basis, not more than 8 per cent of total ash, not more than 0.4 per cent of ash insoluble in hydrochloric acid, nor more than 7 per cent of crude fiber.

5. SWEET CHOCOLATE, SWEET CHOCOLATE COATING. Chocolate mixed with sugar and/or dextrose, with or without the addition of cacao butter, spices, or other flavoring materials. It contains, on the moisture-, sugar-, and fat-free basis, no greater percentage of total ash, ash insoluble in hydrochloric acid, or crude fiber, respectively, than is found in moisture- and fat-free chocolate.

6. MILK CHOCOLATE, SWEET MILK CHOCOLATE. The product obtained by grinding chocolate with sugar and/or dextrose, with the solids of whole milk, or the constituents of milk solids in proportions normal for whole milk, and with or without cacao butter, and/or flavoring material. It contains not less than 12 per cent of milk solids.

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7. COCOA, POWDERED COCOA. Chocolate deprived of a portion of its fat and pulverized. It contains, on the moisture- and fat-free basis, no greater percentage of total ash, ash insoluble in hydrochloric acid, or crude fiber, respectively, than is found in moisture- and fat-free chocolate.

8. "BREAKFAST COCOA." Cocoa which contains not less than 22 per cent of cacao fat.

9. SWEET COCOA, SWEETENED COCOA. Cocoa mixed with sugar and/or dextrose. It contains not more than 65 per cent of total sugars in the finished product, and, on the moisture-, sugar-, and fat-free basis, no greater percentage of total ash, ash insoluble in hydrochloric acid, or crude fiber, respectively, than is found in moisture- and fat-free chocolate.

10. SWEET MILK COCOA. The product obtained by grinding cocoa with sugar and/or dextrose, with the solids of whole milk, or the constituents of milk solids in proportions normal for whole milk, and with or without flavoring material. It contains not less than 12 per cent of milk solids.

11. DUTCH-PROCESS CHOCOLATE, "ALKALIZED CHOCOLATE", and DUTCH-PROCESS COCOA, "ALKALIZED COCOA." Modifications, respectively, of chocolate and cocoa, in that in their manufacture an alkali carbonate or other suitable alkaline substance has been employed. In the preparation of these products not more than 3 parts by weight of potassium carbonate, or the neutralizing equivalent thereof in other alkaline substances, are added to each 100 parts by weight of cacao nibs. The finished products conform to the standards for chocolate and cocoa, respectively, due allowance being made for the kind and amount of alkaline substance added.

Beverages

A. Carbonated Beverages and Beverage Flavors

1. GINGER ALE. The carbonated beverage prepared from ginger ale flavor, harmless organic acid, water, and a sirup of one or more of the following: Sugar, invert sugar, dextrose; with or without the addition of caramel color.

1a. GINGER ALE FLAVOR, GINGER ALE CONCENTRATE. The beverage flavor in which ginger is the essential constituent, with or without aromatic and pungent ingredients, citrus oils, fruit juices, and caramel color.

2. SARSAPARILLA. The carbonated beverage prepared from sarsaparilla flavor, water, and a sirup of one or more of the following: Sugar, invert sugar, dextrose; with or without harmless organic acid, and with or without the addition of caramel color.

2a. SARSAPARILLA FLAVOR. The beverage flavor prepared from oil of sassafras and methyl salicylate (or oil of wintergreen or oil of sweet birch), with or without other aromatic and flavoring substances and caramel color. It derives its characteristic flavor from oil of sassafras and methyl salicylate.

3. ROOT BEER. The carbonated beverage prepared from root beer flavor, water, and a sirup of one or more of the following: Sugar, invert sugar, dextrose; with or without harmless organic acid, and with or without the addition of caramel color.

3a. ROOT BEER FLAVOR, ROOT BEER CONCENTRATE. The beverage flavor in which oil of sassafras and methyl salicylate (or oil of wintergreen or oil of sweet birch) are the principal flavoring constituents. It contains other flavoring substances, with or without the addition of caramel color.

4. BIRCH BEER. The carbonated beverage prepared from birch beer flavor, water, and a sirup of one or more of the following: Sugar, invert sugar, dextrose; with or without harmless organic acid, and with or without the addition of caramel color.

4a. BIRCH BEER FLAVOR, BIRCH BEER CONCENTRATE. The beverage flavor in which methyl salicylate (or oil of sweet birch or oil of wintergreen) and oil of sassafras are the principal flavoring constituents, with or without

other flavoring substances, and with or without the addition of caramel color. The flavor of methyl salicylate predominates.

5. CREAM SODA WATER, "CREAM SODA." The carbonated beverage prepared from cream soda water flavor, water, and a sirup of one or more of the following: Sugar, invert sugar, dextrose; with or without harmless organic acid, and with or without the addition of caramel color.

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5a. CREAM SODA WATER FLAVOR, CREAM SODA WATER CONCENTRATE. The beverage flavor prepared from vanilla, tonka, vanillin, or coumarin, singly or in combination, together with other flavoring substances; with or without the addition of caramel color.

B. WINES

1. WINE. The product made by the normal alcoholic fermentation of the juice of sound, ripe grapes, and the usual cellar treatment. It contains not less than 7 per cent nor more than 16 per cent of alcohol by volume, and, in 100 cubic centimeters (20° C.) not more than 0.1 gram of sodium chloride nor more than 0.2 gram of potassium sulphate; and for red wine not more than 0.14 gram, and for white wine not more than 0.12 gram of volatile acids produced by fermentation and calculated as acetic acid.

a. Red wine is wine containing the red coloring matter of the skins of grapes.
b. White wine is wine made from white grapes or the expressed fresh juice of other grapes.

2. DRY WINE. Wine in which the fermentation of the sugars is practically complete, and which contains, in 100 cubic centimeters (20° C.), less than 1 gram of sugars, and for dry red wine not less than 0.16 gram of grape ash and not less than 1.6 grams of sugar-free grape solids, and for dry white wine not less than 0.13 gram of grape ash and not less than 1.4 grams of sugar-free grape solids.

3. FORTIFIED DRY WINE. Dry wine to which brandy has been added but which conforms in all other particulars to the standard of dry wine.

4. SWEET WINE. Wine in which the alcoholic fermentation has been arrested and which contains, in 100 cubic centimeters (20° C.), not less than 1 gram of sugars, and for sweet red wine not less than 0.16 gram of grape ash, and for sweet white wine not less than 0.13 gram of grape ash.

5. FORTIFIED SWEET WINE. Sweet wine to which wine spirits have been added. By act of Congress, "sweet wine" used for making fortified sweet wine and "wine spirits" used for such fortifications are defined as follows (sec. 43, act of Oct. 1, 1890, 26 Stat. 621; as amended by sec. 68, act of August 27, 1894, 28 Stat. 568; as amended by sec. 1, act of June 7, 1906, 34 Stat. 215; as amended by sec. 2, act of Oct. 22, 1914, 38 Stat. 747; as amended by sec. 402 (c), act of Sept. 8, 1916, 39 Stat. 785; and as further amended by sec. 617, act of Feb. 24, 1919, 40 Stat. 1111):

"That the wine spirits mentioned in section 42 is the product resulting from the distillation of fermented grape juice, to which water may have been added prior to, during, or after fermentation, for the sole purpose of facilitating the fermentation and economical distillation thereof, and shall be held to include the product from grapes or their residues commonly known as grape brandy, and shall include commercial grape brandy which may have been colored with burnt sugar or caramel; and the pure sweet wine which may be fortified with wine spirits under the provisions of this act is fermented or partially fermented grape juice only, with the usual cellar treatment, and shall contain no other substance

whatever introduced before, at the time of, or after fermentation, except as herein expressly provided: *Provided*, that the addition of pure boiled or condensed grape must or pure crystallized cane or beet sugar, or pure dextrose sugar containing, respectively, not less than 95 per centum of actual sugar, calculated on a dry basis, or water, or any or all of them, to the pure grape juice before fermentation, or to the fermented product of such grape juice, or to both, prior to the fortification herein provided for, either for the purpose of perfecting sweet wines according to commercial standards or for mechanical purposes, shall not be excluded by the definition of pure sweet wine aforesaid; *Provided, however*, That the cane or beet sugar, or pure dextrose sugar added for sweetening purposes shall not be in excess of 11 per centum of the weight of the wine to be fortified: *And provided further*, That the addition of water herein authorized shall be under such regulations as the Commissioner of Internal Revenue, with the approval of the Secretary of the Treasury, may from time to time prescribe: *Provided, however*, That records kept in accordance with such regulations as to the percentage of saccharine, acid, alcoholic, and added water content of the wine offered for fortification shall be open to inspection by any official of the

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Department of Agriculture thereto duly authorized by the Secretary of Agriculture; but in no case shall such wines to which water has been added be eligible for fortification under the provisions of this act, where the same, after fermentation and before fortification, have an alcoholic strength of less than 5 per centum of their volume."

6. SPARKLING WINE. Wine in which the after part of the fermentation is completed in the bottle, the sediment being disgorged and its place supplied by wine or sugar liquor and/or dextrose liquor, and which contains, in 100 cubic centimeters (20° C.), not less than 0.12 gram of grape ash.

7. MODIFIED WINE, AMELIORATED WINE, CORRECTED WINE. The product made by the alcoholic fermentation, with the usual cellar treatment, of a mixture of the juice of sound, ripe grapes with sugar and/or dextrose, or a sirup containing not less than 65 per cent of these sugars, and in quantity not more than enough to raise the alcoholic strength after fermentation to 11 per cent by volume.

8. RAISIN WINE. The product made by the alcoholic fermentation of an infusion of dried or evaporated grapes, or a mixture of such infusion or of raisins with grape juice.

VINEGARS

1. VINEGAR, CIDER VINEGAR, APPLE VINEGAR. The product made by the alcoholic and subsequent acetous fermentations of the juice of apples. It contains, in 100 cubic centimeters (20° C.), not less than 4 grams of acetic acid.

2. WINE VINEGAR, GRAPE VINEGAR. The product made by the alcoholic and subsequent acetous fermentations of the juice of grapes. It contains, in 100 cubic centimeters (20° C.), not less than 4 grams of acetic acid.

3. MALT VINEGAR. The product made by the alcoholic and subsequent acetous fermentations, without distillation, of an infusion of barley malt or cereals whose starch has been converted by malt. It contains, in 100 cubic centimeters (20° C.), not less than 4 grams of acetic acid.

4. SUGAR VINEGAR. The product made by the alcoholic and subsequent acetous fermentations of sugar sirup, molasses, or refiners sirup. It contains, in 100 cubic centimeters (20° C.), not less than 4 grams of acetic acid.

5. GLUCOSE VINEGAR. The product made by the alcoholic and subsequent acetous fermentations of a solution of glucose. It is dextrorotatory and contains, in 100 cubic centimeters (20° C.), not less than 4 grams of acetic acid.

6. SPIRIT VINEGAR, DISTILLED VINEGAR, GRAIN VINEGAR. The product made by the acetous fermentation of dilute distilled alcohol. It contains, in 100 cubic centimeters (20° C.), not less than 4 grams of acetic acid.

MISCELLANEOUS PRODUCTS

Salt

TABLE SALT, DAIRY SALT. Fine-grained crystalline salt containing, on a water-free basis, not more than 1.4 per cent of calcium sulphate ($CaSO_4$), not more than 0.5 per cent of calcium and magnesium chlorides ($CaCl_2$ and $MgCl_2$), nor more than 0.1 per cent of matters insoluble in water.[9]

Baking Powder

BAKING POWDER. The leavening agent produced by the mixing of an acid-reacting material and sodium bicarbonate, with or without starch or flour. It yields not less than 12 per cent of available carbon dioxide.

The acid-reacting materials in baking powder are: (1) Tartaric acid or its acid salts, (2) acid salts of phosphoric acid, (3) compounds of aluminum, or (4) any combination in substantial proportions of the foregoing.

FDA'S MONTHLY REPORT OF SEIZURES

A federal grand jury in New York has indicted a corporation and three men as "butterleggers," according to a report released by the Food and Drug Administration on February 25, 1953. The seven-count indictment charged conspiracy to violate the Federal Food, Drug, and Cosmetic Act by labeling colored oleomargarine as pure butter, with intent to defraud consumers. This offense, if proven, carries maximum penalties of $10,000 fine or three years' imprisonment, or both, for each count. One defendant had been enjoined by the federal court at New York City on February 1, 1952, from committing these specific offenses.

Six of eight convictions in January for filthy food shipments involved operating under insanitary conditions which inspectors noted in the factories. The list of January cases includes 17 criminal actions and one injunction terminated in federal courts for other violations of the Act. Eight were based on illegal sales in violation of the prescription-drug provisions of the law. United States marshals made 115 seizures in January of shipments alleged to violate the Federal Food, Drug, and Cosmetic Act and the Federal Caustic Poison Act.

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[9] Pending further announcement, no exception will be taken by the Food and Drug Administration to table salt that meets the requirements of the standard except that it contains anhydrous calcium sulphate (anhydrite) in excess of 0.1 percent, provided that the total calcium sulphate content does not exceed 1.4 percent.

By C. W. CRAWFORD

Legislative and Administrative

THERE is not a great deal to discuss about legislative progress during the past year, although this subject has traditionally been one of the topics your chairman has assigned the representative of the Food and Drug Administration at your annual meeting. No legislation in our field was passed since our last meeting. All pending legislation died with the end of the Eighty-second Congress. The Eighty-third Congress convened only seven weeks ago. We have a new Administrator who has been in office only a month. Both the Administrator and the new Congress are laden with serious new responsibilities of national and world scope, in addition to our problems of food and drug control.

I propose today, therefore, to outline to this group, which is dedicated to the constructive development of food and drug law, some of the *problems* that will come before the legislative and administrative officials in the months to come. From those bills already in the hopper, I can foresee a busy and challenging year for us all.

Of the pending problems, the Federal Security Administrator has had opportunity to consider only that relating to factory inspection. What I shall say about other problems and proposals for their solution cannot be construed as reflecting the views of either the Federal Security Agency or the national Administration. I need hardly point out, however, that any proposed amendment of the Federal Food, Drug, and Cosmetic Act must pass not only the test of desirability on its merits, but also a rigorous scrutiny of its cost.

It is hardly necessary for me to tell this group that our most urgent legislative need is the restoration of factory inspection as a

Progress in 1952

The Dearth of Pertinent Legislative Progress Last Year Causes the Author, Commissioner of Food and Drugs, to Discuss Problems Facing Legislative and Administrative Officials in Coming Months. This Paper was Delivered at the Eighth Annual Meeting of the Section on Food, Drug and Cosmetic Law, New York State Bar Association, New York City, February 20, 1953

right of the people rather than a courtesy of the factory manager. This amendment will obviously make for more effective use of whatever we can spend for enforcement.

Disappointing as the *Cardiff* decision was, much of its aftermath has been deeply gratifying. The press—both general and trade—have been almost unanimous in calling for corrective legislation and have displayed a clear comprehension of the fundamental role of factory inspection as an enforcement tool. We received letters immediately from many manufacturers welcoming our inspectors to continue visiting their plants. Local and state enforcement agencies offered their assistance. Spokesmen of most of the trade associations of the food, drug and cosmetic industries assured their support of prompt remedial legislation.

We know that this reaction stems from an intrinsic desire to hold on to what has proven good for consumer and industry alike. We see in it also a vote of confidence in our inspection staff as a whole, based on its conduct during the past 14 years when it believed that it had the right to inspect factories—and most manufacturers thought so too.

On February 6, Senator H. Alexander Smith and Representative Charles A. Wolverton introduced identical bills (S. 835 and H. R. 2769) recommended by Mrs. Hobby in letters to the President of the

Senate and the Speaker of the House. A similar bill had earlier been introduced by Senator Hubert H. Humphrey (S. 601). These bills would change the language of Section 704 of the Act by simply substituting "after first giving written notice" for the present words "after first making request and obtaining permission." The President, in his state-of-the-union address, called for prompt action to protect the general consumer. I believe it obvious that government and industry should join in a vigorous effort to obtain early enactment.

New Chemicals Reports

As you know, the select committee of the House of Representatives appointed to investigate the problems of new chemicals in foods and cosmetics concluded its hearings early in 1952 and in June issued reports recommending consumer-protection controls similar to those now in effect for new drugs. The committee also recommended expansion of cosmetic safeguards in a number of aspects that will be discussed more fully by the committee counsel, Mr. Kleinfeld, later this morning. Representative Delaney introduced bills (H. R. 2244 and H. R. 2245) covering these recommendations on January 30.

On February 6, Representative Joseph P. O'Hara introduced a bill (H. R. 2739) to amend Section 403 (c), the statutory provision on the labeling of imitations. The Supreme Court decision in the *Imitation Jam* case (340 U. S. 593) held that an article labeled as an imitation of a standardized food, but not conforming to the standard, was immune from the provision of Section 403 (g) against traffic in nonconforming products. H. R. 2739 would close a loophole that is troubling many reputable manufacturers of standardized foods.

Your agenda calls for a discussion of how we can improve our procedures for establishing food standards—particularly how we can shorten the present long-drawn-out hearings and the ensuing delay while the evidence presented can be digested, briefed and presented to all interested parties for comments.

Members of this group have suggested that the Act be amended to provide for more expeditious handling of the noncontroversial parts of the standards. This would be helpful. However, it is the controversial subject in each hearing that takes the months, rather than the hours. In the ice cream hearings, which reopened on January 8, 1951, and closed on December 31, 1952, testimony was received on 207 days.

Of these, 107 days were spent on the *safety* of emulsifiers and four additional days on the safety of other proposed ingredients.

The first pharmacological evidence on the safety of emulsifiers was introduced early in 1948 at the hearings on standards for various salad dressings. This was repeated and greatly expanded in volume in the bread hearings which followed. Some of it appeared for the third time in the ice cream hearings, along with testimony on newer developments.

It has been a costly and wearisome task for all concerned to present, cross-examine and record testimony that is often a duplication and sometimes a triplication of evidence already a matter of public record. In the case of bread, the Administrator refused to admit the polyoxides on the ground that the evidence of safety is not convincing and that their use is likely to be deceptive. The Court of Appeals for the Third Circuit ruled that his action was reasonable. If the Supreme Court agrees, that will be controlling for bread, but there is nothing in our present procedure to prevent month-on-month hearings on other foods in which evidence that is now already on record one, two or three times would be presented along with any later data available. If the safety of chemical additives could be cleared by scientific experts under procedures patterned after those prescribed in the law for new drugs, then the food-standards hearing would involve only the issue of suitability as ingredients of the particular foods under consideration.

Proposals for Agency Reorganization

As you undoubtedly know, there have been several proposals made to Congress relative to reorganization plans concerning the Federal Security Agency. The major one of these will, as announced last week by President Eisenhower, be submitted to Congress in the fairly near future. This plan would transform the Federal Security Agency into an executive department of the federal government. The normal procedure would be for the Congress to consider the Administration-sponsored reorganization plan first. As to what is the position on such reorganization proposals as already have been made or may be made by members of Congress, I do not know, but I am sure that no change will be made without mature and factual consideration of matters affecting the Food and Drug Administration.

Unfortunately, I cannot report progress in building up a force commensurate with our obligations. In common with so many others,

we have had to do more and more with less and less. We have only 205 inspectors on the enforcement roll and 11 on certification, a total of 216, in contrast to a peak of 267 in both groups in late 1951. The number of other employees is geared to the number of inspectors, so we had to reduce our rolls of chemists, bacteriologists, physicians and others to meet reductions in appropriations, increased salary scales and a ceiling on the amount of funds that could be spent on personal services. When I appeared before the Senate Appropriations Committee last February, I stated that it would take our inspectors nine years to cover every establishment producing or warehousing the commodities subject to the Food, Drug, and Cosmetic Act. For every lot that we see produced or sample and examine, there are more than 1,000 that we can't cover. We believe that substantially more than the minute fraction of 1 per cent coverage now given would yield rich returns to the public and to legitimate industry. Important to public welfare as may be some of the proposed legislation I have discussed, I believe there is even greater need for more adequate facilities to enforce the law we now have.

Budget Problems Reflected in Staff Shortages

In saying these things I am in no sense unmindful of the pressing need to approach and then to achieve a balanced budget. I am also aware of the tendency of each bureau chief to think his work deserves top priority. If those who have the broader responsibility decide that strengthening of food and drug enforcement must be delayed, we will, of course, continue to do the best we can with what we are permitted to have. But my report to you would be incomplete if it omitted reference to the staff shortages that keep us from doing so much of what ought to be done.

One of the most difficult phases of administration is the deployment of available resources to achieve the most effective results. A continuing study and adjustment of our own organization and procedures to improve efficiency is only one part of the problem. We must keep abreast of what is going on in the affected industries and of new problems of compliance. We have devoted increased effort to facilitating communications between ourselves and the interested industries. We have appointed in each of the 16 field districts consumer consultants qualified to ascertain and report the views of consumers in their respective communities. They supply us with authentic information about consumer habits, expectations and preferences in regard to label-

ing, purchase and use of foods, drugs and cosmetics. With the sum total of information gained from these varied and comprehensive sources we face the question: From what areas of coverage can man hours be diverted into new and more productive projects? With a shrinking enforcement staff, we cannot hope to increase coverage across the board. I am glad, however, to report progress in concentrating our efforts in the areas of greater need.

Cooperation an Encouraging Factor

In the food field, one of the most encouraging recent developments has been to see industry, state and local agencies, and several federal governmental groups working with the Food and Drug Administration to improve raw stocks to be processed into food. In past years, industry-sponsored sanitation-improvement programs did much to bring factories processing raw stocks to the high degree of sanitation most of them have achieved. Much of the improvement would have been made without regulatory activities, but many campaigns were initiated or intensified after concerted seizures and other court proceedings. Regulatory pressure was necessary to bring performance by the careless and indifferent to the levels willingly achieved by the majority.

A common denominator of our current wheat, corn, and milk and cream sanitation programs is the origin of these commodities in thousands of farms that ordinarily make no interstate shipments. The products are delivered to small collection centers—elevators or cream stations—and the intermingling of lots continues until large deliveries are made to the processors, whose business may be nation-wide. The problem is to improve conditions at the farms, then to protect the products at each step along the way.

Teamwork from Onset of Planning to Completion of Seizure Campaigns

In these new programs the industries and various local, state and federal groups joined in the planning stage. Together we made comprehensive investigations into the nature and scope of the problem. New technical methods were developed and tested for practical use by both industry and government analysts and pest-control people. Through an extensive educational program, in which all groups participated, the problems and the steps being taken to achieve long-range

correction were brought to everyone concerned, from the smallest farmer to the largest mill or creamery operator. Seizure campaigns on contaminated lots was the last step of the program and not the "kick-off."

Participants in the wheat program included the grain trade and farm organizations, the milling industry, food officials in the producing states, three constituents of the United States Department of Agriculture, the Fish and Wildlife Service of the Department of the Interior and the Public Health Service of the Federal Security Agency. The milk and cream program started later and has not reached such extensive participation, but we now have the American Butter Institute, the United States Department of Agriculture, state food officials and state agricultural colleges working with us. Our inspectors are in popular demand as instructors at industry-sponsored cream-grading schools.

We expect these joint efforts to result in cleaner cereal products, butter and cheese in 1953 than we had last year. Such programs cannot reach their goals overnight, but we hope that steady improvement over a period of a few years will bring a level of sanitation satisfactory to consumers of these products.

Another field in which we are embarking on a major cooperative program is the sanitary handling of fresh produce in city markets. The Public Health Service and the Food and Drug Administration are working actively on preliminary plans. The Department of Agriculture has already completed extensive investigations. The program will depend substantially on the activities of local and state food and health groups, and they are indicating a very wholehearted interest.

Over-All View of Year's Enforcement Progress

As to enforcement operations as a whole in the calendar year 1952, 8,343 tons of filthy or decomposed foods were seized—nearly 27 tons every weekday. Also seized were more than 50 carloads of wheat contaminated with a poisonous mercurial compound used for seed treatment. This brings the total to more than 10,500 tons of food removed from consumer channels because it was unfit for the public to eat. About 44 per cent of the filthy or decomposed food seized left the producing and processing establishments in fit condition and became adulterated during storage at destination.

Nearly a thousand tons of food were seized on other charges, which included excess water in oysters, poultry and butter; fake sor-

ghum; diluted lemon oils; products failing to meet the specifications of official standards; and short weight in various items. One of the most significant criminal cases of the year in the field of economic cheats terminated in conviction of three individuals who were ringleaders in the Middle West horse-meat scandals. We had convincing evidence of the violation—an FDA inspector actually witnessed the defendants in the act of trying to obliterate every marking and telltale sign that would distinguish horse meat from beef. The circuit court which upheld the conviction stressed the government's factory-inspection evidence.

Eighty per cent of our criminal cases on drugs last year were brought against firms and individuals charged with illegal retail sales. Each case was supported by a history of acts detrimental to the community. Many of the purchasers had backgrounds of juvenile delinquency, or hospital or police records, that indicated use of barbiturates, amphetamines and other prescription drugs for nonmedical purposes.

We have carried out for many years a campaign of education—assisted by national trade associations and state pharmacy groups—to apprise every pharmacist of his obligation to limit his sales of prescription drugs to proper uses. Now, with the wide publicity given to the passage of the Durham-Humphrey Amendment and the explicit labeling it requires, those who formerly pleaded ignorance of the law have no further excuse. Illegal sales in the future will be deliberate. Attempts to avoid detection will be increasingly determined. Our inspectors have already been subjected to physical violence from underworld characters who have persisted in illegal operations. It is interesting to note that they are not protected, as narcotics agents and other federal investigators are, with a federal law prohibiting physical attack.

Cancer Quacks as Investigation Target

Progress has been made this year in the war against cancer quacks. In the old days there were numerous nostrums on the shelves of every corner drugstore which promised cure of cancer, diabetes, tuberculosis and other dread diseases. The nostrums have been moved to treatment centers in various guises—tourist camps, bathhouse sanitariums and phony "clinics." As long as they operate on a local basis we cannot act, but when they become popular they attract visitors from other states, and, after the initial diagnosis and treatment, it is profitable for the operators to have their patients continue with home medication.

The Supreme Court has recently refused to review two circuit court opinions upholding the proposition that articles come under federal jurisdiction when they are delivered with knowledge that they are to be transported to out-of-state places. Another circuit court ordered an injunction against shipments by one of the most notorious cancer sanitarium operators, and on February 2 the Supreme Court denied his petition for certiorari.

Only last month an "herb doctor" was sentenced to a year in jail for his false and misleading cancer-cure claims. In this case, as in the others, we brought pitiful case histories to the courtroom showing the irreparable harm caused by mistaken reliance on the nostrum. In the "herb doctor" case a physician testified that he had recommended an operation when his patient's cancer was still operable. Instead, she had turned to the herb treatment and at the time of the trial was on her deathbed.

We are not through with the war on cancer quacks and their victimization of the American public. Investigations are coming to a conclusion in several other cases, which we shall make every effort to crown with equal success.

Revised Labeling for Chloramphenicol

A nation-wide survey last summer uncovered 177 cases of serious blood disorders and fatalities associated with use of the antibiotic chloramphenicol. We asked the National Research Council to evaluate these cases. On the recommendation of a special committee of the council, distribution of chloramphenicol was continued under revised labeling which cautions physicians against unnecessary risks.

The council also recommended that further study of serious reactions to this and other drugs be promoted. A new drug hailed as "miracle" or "wonder" may reach millions of people within a short time. This gives emphatic point to two questions: Will reactions parallel those of patients in the carefully controlled clinical tests made to establish safety before the new-drug application was submitted? Will use of the drug be limited to conditions for which it has been shown suitable or will there be "shotgun" administration for minor infections or conditions entirely outside its known range of efficacy?

Many of the fatalities in the chloramphenicol cases were tragically unnecessary, because of irrational and indiscriminate use—in some cases by persons who had access to supplies, such as hospital attendants, and in others on bona fide prescriptions. The same situation has existed for other antibiotics, sulfonamides and other potent drugs.

Tragedy Points Need for Continued Education of Consumers

Valuable new drugs should not be withheld from the market because there may be this type of misuse, but we do need strengthened educational efforts to minimize the potential harm. We need also increased facilities to obtain more completely the information available in the records of hospitals and clinics on the nature, severity and incidence of drug injuries. The published literature and the incidental cases which are reported to us are insufficient for a clear picture, and there is now no agency, governmental or otherwise, that systematically collects and compiles this information.

Studies of potential danger should not be confined to drugs. There are new therapeutic devices being distributed today, and others under development, of which not enough is yet known to assure safe use. We are at present very much concerned about radioactive devices and ultrasonics. As a minimum control measure, these should not only be restricted to persons capable of using them without causing damage, but accurate equipment for measuring output of emanations or vibrations should be available so that the experts can control dosages and evaluate the efficacy of the treatment. We have added to our staff a physicist who, with our medical officers, has been receiving the generous cooperation of specialists in these fields.

These are but a few of the highlights of our activities last year and of the problems that confront us. The 1952 Annual Report, which we hope will be available for distribution in a week or so, contains many more facts and figures about our activities which I hope you will study. As for the problems, I am confident that we will continue to receive the constructive help that has always been so generously given by members of this group to make our actions increasingly responsive to public needs. **[The End]**

• MISREPRESENTATION—DRUGS •

A manufacturer of weight-reducing tablets has been directed to stop advertising that its tablets will prevent the development of a tired or rundown feeling, except when such conditions result solely from vitamin or mineral deficiencies. (Initial order released February 27, 1953.) Another manufacturer of such tablets has agreed to discontinue advertising claims that its condensed tablets possess weight-reducing properties. (Released March 13, 1953.) The seller of a skin preparation has agreed to stop advertising that its product will prevent or remove all externally caused blemishes. (Released February 27, 1953.)—CCH TRADE REGULATION REPORTS, ¶ 11,341, 16,681, 16,678.

By A. M. GILBERT

Statement Resolution

MR. CHAIRMAN, and members of the Food, Drug, and Cosmetic Law Section of the New York State Bar Association:

As we all know, the President of the United States has reactivated the subject of the reorganization of the executive branch of the government, and it has been indicated that further consideration will be given to the proposals heretofore made by the Hoover Commission which have not as yet been acted upon.

I know that there is not one of us here who does not want to see an improvement in the executive branch of our government and, wherever possible, an elimination of unnecessary expenditures. However, one of the recommendations of the Hoover Commission, submitted with vigorous dissent, was that the jurisdiction of the Food and Drug Administration be split up, with its responsibilities over foods being assigned to one government agency and its regulation over drugs and cosmetics going to another government agency.

In the present Congress, Mr. Hoffman of Michigan has introduced H. R. 292, which provides for a reorganization of the Department of Agriculture. Section 14 of that bill provides that the Secretary of Agriculture is authorized and directed, in conjunction with the Federal Security Administrator and the Federal Trade Commission, to study the diverse requirements and procedures and overlapping authority of the various federal agencies in connection with the exercise of regulatory functions with respect to food products and drugs, with a view to submission to the Congress of a plan for placing regulatory functions respecting food products under the Department of Agriculture and those respecting drugs under the Public Health Service. I might

and

on FDA

A Resolution on the Inadvisability of the Proposed Split-up of FDA Jurisdiction Was Presented in a Speech at the Annual Meeting of the Section on Food, Drug and Cosmetic Law, New York Bar Association, February 20 by the Author, a Member of the New York Law Firm of Davis & Gilbert

add that Mr. Hoffman also introduced H. R. 301 which would establish a department of health and would transfer to this new department the Public Health Service and the facilities and functions of the Federal Security Administrator in relation thereto.

I know I speak for all when I say that it would be most inadvisable to have the authority of the Food and Drug Administration split up and divided between two or more government agencies. This would not be an improvement in the executive branch of our government; it would be just the opposite, in that it would result in increasing government expenditures and, even more important than that, it would cause a serious diminution in the effective enforcement of our food and drug laws. I do not think it necessary to mention what has been stated at our meetings so many times, that the Food and Drug Administration has done an outstanding job in its administration and enforcement of the food and drug laws. In view of the experience of our membership, I do not think I have to go into detail or labor the point.

Inasmuch as our section is the oldest organization of lawyers devoted to our food and drug laws, I think we should express our opinion on this subject at the proper time, and such opinion should be transmitted to those in the executive and legislative branches of our government who may be considering any proposal to split up the Food and Drug Administration.

Accordingly, I submit to the membership the following resolution and move its adoption:

Resolution for Consideration and Action at the February 20, 1953 Meeting of the Food, Drug and Cosmetic Law Section of the New York State Bar Association

WHEREAS, the enforcement of the Federal Food and Drug Laws, since their very inception, always has been vested in a single government agency, the Food and Drug Administration and its predecessors, and

WHEREAS, the Food and Drug Administration, composed of experienced, skilled and scientifically trained officers and personnel, during approximately the past half-century has administered and enforced the Federal Food and Drug Laws with distinguished success, and

WHEREAS, experience has clearly demonstrated over the course of years that it is advisable that the jurisdiction over foods, drugs, cosmetics and devices continue to vest in a single government agency in order to promote efficiency and to avoid unnecessary expenditure of government funds, and

WHEREAS, it has been suggested that the regulatory functions respecting food products be placed under one government agency and those respecting drugs be placed under another government agency, and such proposal, or a similar one, may be submitted to the Congress by way of one or more bills or a Presidential reorganization plan, and

WHEREAS, the Food, Drug and Cosmetic Law Section of the New York State Bar Association, the original organized group of lawyers interested and specializing in problems under and the enforcement of the Food and Drug Laws of this country, on the basis of its experience and knowledge, is of the firm opinion that any such proposal would be most inadvisable and, if adopted, would result in decreasing efficiency, unnecessary overlapping jurisdictions, conflicting interpretations, and waste of government funds,

NOW, THEREFORE, BE IT RESOLVED by the Food, Drug and Cosmetic Law Section of the New York State Bar Association that it hereby registers its considered and firm opinion that it would be inadvisable in the best interests of good and sound government to divide between two or more government agencies the present jurisdiction of the Food and Drug Administration over food, drugs, cosmetics and devices.

BE IT FURTHER RESOLVED that the proper officers of this Section be and they are hereby authorized to express the opinion of this Section on the aforementioned subject to any and all executive and legislative officers and groups which may at any time hereafter consider this subject. **[The End]**

Judicial, Administrative and Legislative Developments

Significant Comments

By THOMAS W. CHRISTOPHER

Court Decisions

There is not much in the *Cardiff* decision [1] to warrant analysis, for it is a straight "no" decision with little elaboration. The technical approach by the United States Supreme Court is in sharp contrast to its attitude in the *Sullivan* case, for in the latter decision the Court made a point of looking at the spirit of the statute rather than at legalities. In fact, it could be contended with considerable logic that the attitude of Mr. Justice Frankfurter in his dissent in the *Sullivan* case now represents the attitude of at least seven justices. Too, when the *Cardiff* opinion speaks of the "vice of vagueness in criminal statutes," another dissenting opinion comes to mind—that of Mr. Justice Murphy in the *Dotterweich* case. Actually, these two dissents are quite similar in their philosophy, although Justice Frankfurter wrote the majority opinion in the *Dotterweich* case.

From the point of view of administrative law, the *Cardiff* opinion is significant in that it is another indicant that the Supreme Court is beginning to tighten up its supervision of administrative tribunals, or at least to level off in its liberal treatment of these agencies. However, it would be risky to make too much of "trend." It is a salutary practice to remember that Holmes himself sometimes was extremely technical in food and drug [2] and other administrative cases, and at other times was the opposite.

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[1] *U. S. v. Cardiff*, 73 S. Ct. 189 (December 8, 1952).

[2] See *U. S. v. Johnson*, 221 U. S. 488 (1911), Kleinfeld & Dunn, *Federal Food, Drug, and Cosmetic Act, 1949-1950*, p. 26.

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Standards.—The *Glyco Products Company (Atlas Powder Company)* decision [3] is one about which lawyers may argue for hours, for it involves a novel theory and includes some rather forceful logic, both by the court and by counsel. The key facts are simple. In the standards of identity for bread, the Administrator allowed "glyceride" bread softeners as optional ingredients, but disallowed "polyoxide" softeners. The makers of the latter appealed.

The petitioner advanced the neoteric thesis that a standard of identity is only concerned with the ingredients and proportions of ingredients which are characteristic of the species and that the accomplishment of standardization is not affected in any significant way by the inclusion or exclusion of less consequential ingredients which do not change the essential description or properties of the food. Thus, the addition of a "polyoxide" softener involves no departure from the standard, since the food is still bread and, essentially, the same kind of bread.

The court answers this contention partly by use of analogies and partly by the pragmatic test of workability. In the analogy category the court says that by this theory vitamins could be added at will to a cereal. This would appear to be a doubtful analogy, as one would think that vitamins would change the essential properties, whereas the bread softener in question merely causes the bread to remain soft longer. A second comparison involves the use of preservatives in catsup, and this appears to be closer to home. In the practical category,

[3] *Glyco Products Company v. Federal Security Administrator and Atlas Powder Company v. Ewing*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7247 (CA-3, December 22, 1952) (petition for certiorari has been filed).

the court states that standards would become legal snares by this theory—that it would be next to impossible to have standards as there would be too many borderline ingredients. The court concludes: "we are convinced that all ingredients proposed for use in the fabrication of a food are comprehended by the administrative process of standardization."

The petitioner's theory is an interesting one, and it has intellectual appeal. But it is clear that its acceptance would toll the death of standards as we now know them and substitute a new and more narrow approach. A person doesn't need a standard to tell him that flour goes into bread or tomatoes into catsup. One of the primary purposes of this type of regulation, as now used, is to set up fences for optional and borderline ingredients. This is not to say that standards would be useless under this theory but, rather, that its acceptance would mean a new concept for, and approach to, the idea of standards of identity.

The petitioner made a second attack on Section 401 on the ground that it was an invalid delegation of legislative power. The claim is that adequate guides are not contained in the statute. He appears to admit that the guides are sufficient as to the required ingredients but maintains that they are insufficient as to the optional ones. The administrative discretion, he states, in designating optional ingredients may be exercised at will without meaningful legislative control and guidance.

The court replies to this charge by saying: "the very data measured by the same legislative yardsticks that lead to rigid standardization for one food may as clearly show the propriety of flexibility in the form of permissive variations of composition in another." It adds that all variations allowed by a standard, whether in percentage required, substitution of ingredients or option to include or omit, are governed by the same criteria of reasonableness and protection of consumer interests.

The court's reasoning here is forceful. The word "reasonable" and the phrase "promote honesty and fair dealing in the interest of consumers," as found in Section 401, apply to both the required and the optional ingredients—thus, the standard in its entirety. It is not easy to see how the guides can be adequate for one and not for the other.

The decision is now on appeal.

Labeling.—Another case worthy of special notice, *U. S. v. Kocmond*, involves an unusual fact situation.[4] The defendant dealer, subsequent

[4] *U. S. v. Kocmond*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7249, 200 F. (2d) 370 (CA-7, 1952) (petition for certiorari has been filed).

to the sale but prior to delivery of horse meat to the buyer, removed the labels from the barrels of meat and from the meat itself. This was done with the knowledge and at the direction of the buyer. There was no evidence that the buyer purchased the meat for his own consumption.

A criminal information was filed under Sections 301 (k) and 403 (a), 403 (e) (1) and 403 (i) (1) of the Act.

The defendant dealer maintained that title had passed to the buyer at the time the labels were removed and so the product was no longer "held for sale" under the meaning of Section 301 (k).[5]

The court rejected this interpretation on the ground that the label was removed before the goods reached the ultimate consumer. ". . . we are not concerned here with the niceties of the mechanics governing the completion of sales of personal property. We are concerned with whether or not defendants, whether they were then the owners of the merchandise or not, did remove the labels while the goods were still held for sale."

Petition for certiorari has been filed, but perhaps a few remarks on the decision will not be out of order. In the *Sullivan* decision the label was removed before the sale was consummated between the parties. Here, the label was removed after the sale on direction of the buyer. If the decision is upheld, the transcript of record in the case (which I have not seen) will merit careful study, for what now appear to be significant overtones may be washed out by such study. At any rate, this appears to be the "sleeper" case to watch and study.

Adulteration.—In *Berger v. U. S.*,[6] the constitutionality of Section 402 (a) (4)[7] was challenged as violating the Sixth Amendment,[8] it being said that the section is so indefinite, uncertain and obscure that it does not inform one accused thereunder of the nature and cause of the accusation. "It is contended that because the statute leaves

[5] Sec. 301 (k): "The following acts and the causing thereof are hereby prohibited: . . . (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded."

[6] CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7248 (CA-8, December 30, 1952).

[7] Section 402 (a) (4): "A food shall be deemed to be adulterated (a) . . . (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health."

[8] "In all criminal prosecutions, the accused shall enjoy the right to . . . be informed of the nature and cause of the accusation . . . ."

open for determination the *degree* of insanitation which would possibly or probably result in contamination, it does not meet the test of definiteness." In plain words, a producer has to *guess* at the degree of cleanliness necessary to stay within the statute, and he takes a chance that a jury will disagree with him. The argument also is put in another way, namely, that the statute contains no definition of "insanitary conditions," and so a person cannot tell in advance when a condition violates the prohibition.

The court replies to these contentions by stating: "The terms 'insanitary conditions' and 'contaminated' are descriptive terms commonly used and understood. . . . the fact that a statute contains in its definition an element of degree as to which estimates may differ does not result in unconstitutional indefiniteness or uncertainty." The court also states: "the law is full of instances where a man's fate depends on his estimating rightly, that is as the jury subsequently estimates it, some matter of degree."

False Advertising.—Two cases deserve brief mention under this heading. In one, it was held that cigarettes are not within the Federal Trade Commission Act's definition of a "drug," even though tobacco is listed in the Homeopathic Pharmacopoeia.[9] The definition of a drug given in Section 15 of the Federal Trade Commission Act [10] is exactly the same as that given in Section 201 (g) of the Food and Drug Act, and so the decision has significance for both acts.

The second decision brought a halt to a proceeding against Carter Products, Inc., at least temporarily and subject to appeal. The Court of Appeals for the Ninth Circuit set aside the commission's cease-and-desist order on the grounds that the respondent had not had a fair hearing. It was not a fair hearing, the court held, in that the right of defense council to cross-examine government witnesses was too much restricted.[11]

Administrative Action

FDA.—Of special interest to those who make a study of the administrative methods of the FDA, as well as to affected parties, is the fact that after long and careful investigation the FDA is beginning enforcement under its program for greater sanitation in the milling

[9] *FTC v. Liggett & Myers Tobacco Company*, 1952 TRADE CASES ¶ 67,377, 108 F. Supp. 573 (DC N. Y., 1952).

[10] 38 Stat. 717 (1914), as amended, 15 USC 41, and following (1946).

[11] *Carter Products, Inc. v. FTC*, 1953 TRADE CASES ¶ 67,421 (CA-9, January 19, 1953).

industry. Of unusual interest to an outsider is the fact that this entire program, including enforcement, has been worked out in cooperation with the affected industry.

It also should be noted that the FDA has ruled that drugs intended for export are not exempt from the "new drug" provisions of the Food and Drug Act.[12]

FTC.—In the Federal Trade Commission it is apparent that the commission is still adhering to a doctrine which was rejected in 1950 by one court of appeals in the *Alberty* decision.[13] In the *Alberty* case the FTC had required that the advertising of a drug indicate that more than likely the disease was not caused by the deficiency for which this drug was a remedy. The court held that the commission could not make this negative requirement. The Supreme Court refused certiorari. It now appears from recent actions that the commission has not discarded this device but continues to make such requirements,[14] perhaps in the hope of securing a Supreme Court ruling.

Congress

The proposed amendment to the Food and Drug Act to remedy the situation created by the *Cardiff* decision [15] is direct and simple. It would strike from Section 704 the words "after first making request and obtaining permission of" and insert in lieu thereof the words "after first exhibiting appropriate credentials to." Unless it is constitutionally defective, this amendment would appear to be adequate to restore the inspection powers of the FDA.

The Hoover Report recommendations for splitting up the FDA appear to be coming to the front again in this Congress (although the present proposals are slightly different from those of the Hoover Report). The primary effect of the present moves would be to split up the FDA between the Public Health Service and the Department of Agriculture. **[The End]**

[12] See CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7244.

[13] *Alberty v. FTC*, 1950-1951 TRADE CASES ¶ 62,583, 182 F. (2d) 36 (CA of D. C., 1950), cert. den., 340 U. S. 818 (1950).

[14] See *The Thornton Company*, FTC Dkt. 6004 (December 2, 1952).

[15] H. R. 3551, February 26, 1953.

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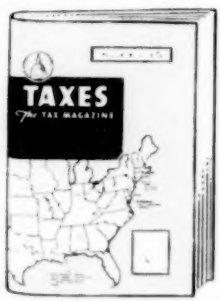

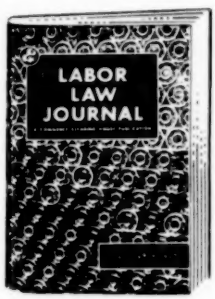

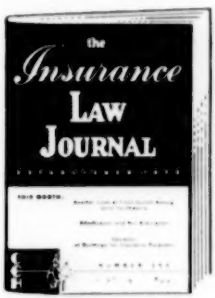

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